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(54) Title: COMPRESSIBLE TISSUE ANCHOR ASSEMBLIES

(57) Abstract: Apparatus & methods for optimizing anchoring force are described herein. In securing tissue folds, over-compression of the tissue directly underlying the anchors is avoided by utilizing tissue anchors having expandable arms configured to minimize contact area between the anchor and tissue. When the anchor is in its expanded configuration, a load is applied to the anchor until it is optimally configured to accommodate a range of deflections while the anchor itself exerts a substantially constant force against the tissue. Various devices, e.g., stops, spring members, fuses, strain gauges, etc., can be used to indicate when the anchor has been deflected to a predetermined level within the optimal range. Moreover, other factors to affect the anchor characteristics include, e.g., varying the number of arms or struts of the anchor, positioning of the arms, configuration of the arms, the length of the collars, etc.



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## COMPRESSIBLE TISSUE ANCHOR ASSEMBLIES

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. Pat. App. Serial No. 11/179,082 filed July 11, 2005, which is a continuation-in-part of U.S. Pat. App. Serial No. 10/865,243 filed June 9, 2004, each of which is incorporated herein by reference in its entirety.

### FIELD OF THE INVENTION

[0002] The present invention relates to improved tissue anchors for securement against tissue. More particularly, the present invention relates to tissue anchors which are deployable into or against tissue for securing portions thereof.

### BACKGROUND OF THE INVENTION

[0003] Morbid obesity is a serious medical condition pervasive in the United States and other countries. Its complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy.

[0004] A number of surgical techniques have been developed to treat morbid obesity, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0005] Furthermore, the sutures or staples that are often used in these surgical procedures typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue. Moreover, the tissue underlying the suture or staple may be subject to becoming over-compressed to the point of becoming subject to necrosis. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured without necrosing the approximated tissue. The gastrointestinal lumen includes four tissue layers, wherein the mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer and the serosa layer.

[0006] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid muscularis and/or serosa layer should ideally be engaged. This problem of capturing the muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intraoperatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs. Thus, an anchor is desirably non-traumatic to the surrounding tissue. Moreover, the anchor is also desirably strong enough to withstand the movement of the tissue.

[0007] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the suctioned tissue in a folded condition known as a plication. Another method involves manually creating sutures for securing the plication.

[0008] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the body lumen. In the period of time that a patient is anesthetized, procedures such as for the treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a minimal level of confidence.

[0009] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication will not relax under any slack which may be created by slipping staples, knots, or clips. Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc. are also often used to prevent sutures from slipping

through tissue. However, many of these types of devices are typically large and unsuitable for low-profile delivery through the body, e.g., transesophageally. Moreover, these methods do not allow the surgeon to gauge the amount of force being applied to or against the tissue by the sutures, staple, clip, etc. Thus, over-tightening of the tissue anchor against the underlying tissue surface may be problematic.

[0010] Moreover, when grasping or clamping onto or upon the layers of tissue with conventional anchors, sutures, staples, clips, etc., many of these devices are configured to be placed only after the tissue has been plicated and not during the actual plication procedure.

### SUMMARY OF THE INVENTION

[0011] In securing the tissue folds or anchoring to or from these tissue folds or plications, over-compression of the tissue directly underlying the tissue anchors is preferably avoided. Over-compression of the underlying tissue may occur if the anchor compresses the tissue to such a degree that tissue necrosis or cutting of the underlying muscularis or serosal tissue by the anchor occurs. Accordingly, a tissue anchor is preferably configured to maintain or secure a tissue plication yet still allow for adequate blood flow to occur within the tissue underlying the anchor. As such, the tissue anchor is preferably configured to accommodate a range of deflections due to various movements of the tissue due to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc., while maintaining or exerting a substantially constant force against the tissue.

[0012] A particular type of anchor which may be utilized is a reconfigurable "basket"-type anchor generally having a number of configurable struts or legs extending between at least two collars or bushing members. This anchor may have a low-profile delivery configuration and a radially expanded anchoring configuration. When expanded, each arm of the anchor may be separated from one another by a spacing or opening. The spacing is preferably created to minimize the contact area between the anchor body and the underlying tissue surface to allow for greater blood flow in the tissue and to inhibit necrosis of the tissue.

[0013] The anchor may be made from various materials, e.g., spring stainless steel, plastics such as polyurethane, nylon, etc., but is preferably made from a shape memory or superelastic alloy, e.g., Nitinol. The anchor may thus be shaped and heat-set such that it self-forms or automatically configures itself from the delivery

configuration to the expanded configuration upon release of a constraining force, e.g., when the anchor is ejected from its delivery needle or catheter. Sutures may connect a proximal anchor to a distal anchor through the tissue fold to secure the plication.

5 [0014] When the anchor has been configured into its expanded configuration, a load or force may be applied to the anchor until the anchor has been optimally configured to accommodate a range of deflections while the anchor itself maintains or exerts a substantially constant force against the tissue. Anchor deflection may occur, e.g., when the proximal and distal collars of an anchor have been advanced or urged towards one another such that the arms or struts extending therebetween are at least  
10 partially deflected. Moreover, anchor deflection may be due to various movements of the tissue attributable to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc.

[0015] Knowing the anchor deflection-to-exerted force characteristics for a given anchor, one may load an anchor with a tension or compression force such that  
15 subsequent deflections of the underlying tissue being anchored occur within specified ranges, such as the optimal range. For instance, an anchor may be pre-loaded such that tissue fluctuations or movements occur within the optimal window or range where the force exerted by the anchor remains relatively constant over a range of deflections. This in turn may ensure that the underlying tissue is not subject to over-  
20 compression by the anchors.

[0016] One method for limiting the loading or pre-load force upon an anchor may involve including a post or stop in the anchor body which limits the proximal deflection of the distal collar and thus prevents over-compression of the anchor against the tissue. Another variation may utilize friction-producing regions within the  
25 anchor delivery catheter. As the anchor is tensioned, various regions may produce frictional forces which vary in accordance to the degree of anchor deflection. A change in the detected frictional force may thus be utilized to indicate that anchor has been configured within an optimal range of deflections.

[0017] Another variation may include the use of a spring member having a  
30 known spring constant or fuse-like member which are set to break or fail at predetermined levels of detected force to detect the amount of deflection an anchor has undergone. Alternatively, measurement of material deformation via strain gauges may also be utilized to determine the amount of deflection. The anchor tensioning

assembly may thus be configured to indicate when the anchor has been deflected to a predetermined level, when the anchor has been deflected within the optimal range.

[0018] Yet another variation may include configuring the proximal collar of the anchor to prevent the passage of stop member contained within the anchor. thus, the length of suture extending from the stop member to the attachment point within the anchor may be of a predetermined length such that when the stop member is seated against the proximal collar, the suture length may compress the anchor into a predetermined deflection level. This deflection level may be preset to configure the anchor to any desired configuration, as described above.

[0019] The anchors may be tensioned through various methods. One particular method may include tensioning the anchors via an elongate rigid or flexible shaft having a hollow lumen. A tensioning mechanism, which is configured to receive the anchors and grasp a tensioning suture, may be positioned near or at the distal end of the elongate shaft. After the anchor or anchors have been desirably tensioned, the shaft may simply be removed from the body.

[0020] Various other factors of the tissue anchors may be modified to affect the tensioning and loading characteristics when deflecting the anchors. Moreover, some of the factors may also affect the interaction of the anchor with respect to the tissue in ensuring that the tissue is not over-compressed and that adequate blood flow may occur within the tissue directly beneath the anchor. Some of the factors may include, e.g., varying the number of arms or struts of the anchor, positioning of the arms, configuration of the arms, the length of the collars, etc.

[0021] Moreover, exposed portions of the anchor may be optionally coated or covered with a material to protect against exposure to foreign materials, e.g., food or other object which may be ingested by the patient, other surgical tools, etc. Accordingly, a biocompatible coating or covering may be placed over the entire length of the anchor arms or only along the portions of the arms not against the tissue. Alternatively, a mesh or skirt-like covering may be placed over the exposed portion of the anchor or the entire anchor itself may be covered with a distensible or expandable covering or mesh.

[0022] In another variation, a separate mesh basket and basket anchor may be assembled as a hybrid combination where the basket anchor is placed within the mesh basket such that they are freely floating with respect to one another. Alternatively, one or both collared ends of both baskets, i.e., the basket anchor and mesh basket,

may be formed or otherwise adhered to one another. In yet another variation, a mesh basket, alone or in combination with a basket anchor, may be pre-formed to compress into a ringed configuration which inhibits or resists being pulled through a tissue region when deployed and compressed against the tissue surface. In these and other variations, a biasing element such as a spring may also be utilized to connect the collars of the mesh anchor to one another. Use of a spring may facilitate at least the partial expansion of a mesh anchor when deployed or released from the deployment instrument and inhibit the anchors from being pulled through a tissue region.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Figs. 1A and 1B show perspective views of an example of a basket-type anchor in a delivery configuration and an expanded configuration, respectively.

[0024] Fig. 2A shows a cross-sectional side view of one variation for delivering a basket anchor through a needle for anchoring to a fold of tissue.

[0025] Fig. 2B shows a cross-sectional side view of examples of how basket anchors may be utilized in anchoring tissue plications.

[0026] Figs. 3A and 3B show a graph of initial displacement or deflection versus exerted force and an example of a tissue anchor correspondingly displaced, respectively.

[0027] Figs. 4A and 4B show the graph illustrating an optimal range of anchor deflection where the exerted force by the anchor remains substantially constant and the correspondingly compressed anchor, respectively.

[0028] Figs. 5A and 5B show the graph illustrating the rising force for an over-compressed anchor and the correspondingly compressed anchor, respectively.

[0029] Figs. 6A and 6B show cross-sectional side views of an anchor having a center post extending within the anchor for limiting the compression of the anchor.

[0030] Figs. 7A and 7B show cross-sectional side views of one variation of an anchor tensioning or loading mechanism utilizing different frictional coefficients to indicate the load placed upon the anchor.

[0031] Figs. 8A and 8B show the corresponding frictional force generated utilizing the device of Figs. 7A and 7B, respectively.

[0032] Fig. 9 shows a partial cross-sectional view of another variation of an anchor loading mechanism which utilizes a spring member having a known spring constant.

[0033] Fig. 10 shows a partial cross-sectional view of another variation of an anchor loading mechanism utilizing a strain gauge for measuring the strain, and the resultant load, exerted upon the anchor.

5 [0034] Fig. 11 shows a cross-sectional view of another variation of an anchor loading mechanism which utilizes a stop for limiting the anchor compression to a predetermined limit.

[0035] Figs. 12A and 12B show partial cross-sectional views of another variation of an anchor loading mechanism utilizing a fuse-like device set to break or release upon reaching a predetermined load.

10 [0036] Figs. 13A and 13B show side views of various notched fuse-members which may be utilized with the variation of Figs. 12A and 12B.

[0037] Fig. 14A shows a partial cross-sectional side view of a device which may be used to apply the load upon the loading mechanism.

15 [0038] Fig. 14B shows a perspective view of an alternative loading mechanism.

[0039] Fig. 14C shows a side view of an assembly in which the loading mechanism may be placed for applying the load upon the anchors.

[0040] Figs. 15A and 15B show side and edge views, respectively, of one variation of a basket anchor in a flattened and splayed view

20 [0041] Fig. 15C shows a perspective view of the anchor of Figs. 15A and 15B in its delivery configuration.

[0042] Figs. 16A and 16B show side and edge views, respectively, of another variation of a basket anchor in a flattened and splayed view

25 [0043] Fig. 16C shows a perspective view of the anchor of Figs. 16A and 16B in its delivery configuration.

[0044] Figs. 17A to 17J show cross-sectional end views of the proximal (I), middle (II), and distal (III) portions of a single anchor strut or arm showing some of the various shapes that the anchor strut or arm may be configured.

30 [0045] Figs. 18A to 18F show examples of end views of anchors having an increasing number of struts or arms.

[0046] Figs. 19A to 19F show examples of side views of anchors having various strut or arm configurations.

[0047] Figs. 20A and 20B show side views of anchors having various configurations affected by the heights of the anchor collars.



[0048] Fig. 21A shows a perspective view of an anchor in an expanded configuration having a protective coating or covering over at least a portion of the struts or arms.

[0049] Fig. 21B shows a perspective view of another anchor having a protective covering or mesh over at least a portion of the anchor facing away from the tissue surface.

[0050] Fig. 21C shows a perspective view of another anchor having a protective covering or mesh over the entire anchor body.

[0051] Fig. 22A shows an example of a combination hybrid basket assembly.

[0052] Fig. 22B shows the basket assembly of Fig. 22A formed with a second basket assembly with a length of suture routed therebetween for tissue securement.

[0053] Fig. 23A shows the basket assembly of Fig. 22A with detail views of either collar ends.

[0054] Figs. 23B and 23C show the basket assembly of Fig. 23A in use with another similar anchor in an apposed configuration in approximating a portion of tissue into a serosa-to-serosa tissue fold.

[0055] Fig. 24A illustrates a side view of another hybrid basket assembly having a mesh anchor with a basket anchor contained within having arm members or struts which are formed in a curved, spiraled, or arcuate shape between the collars.

[0056] Fig. 24B shows the basket assembly of Fig. 24A compressed into its disk-shaped configuration with curved or spiraled arm members compressed into a looped, spiraled, or flower-shaped configuration.

[0057] Fig. 25A illustrates a low-profile configuration of an anchor having one or more radially-biased bulges pre-formed between at least one inwardly-biased radius.

[0058] Figs. 25B and 25C show the basket of Fig. 25A in compressed side and top views, respectively.

[0059] Figs. 26A and 26B show the basket anchor of Fig. 25A having an additional ring, band, or other restraining structure integrated or otherwise attached to the mesh.

[0060] Fig. 27A to 27C show an anchor assembly in its low-profile configuration with a spring element connecting the collars of the anchor and a partially compressed anchor where the collars have been drawn or urged towards one another by the spring element, respectively.

[0061] Figs. 28A to 28C show the anchor of Figs. 25A to 25C also including a spring element connecting the collars of the anchor.

[0062] Fig. 29 shows a partial cross-sectional view of the anchors of Figs. 28A to 28C disposed within a needle lumen.

5 [0063] Figs. 30A and 30B illustrate anchors which are partially expanded by the spring elements prior to being approximated towards one another to secure a tissue fold.

#### DETAILED DESCRIPTION OF THE INVENTION

10 [0064] Generally, in creating and securing a plication within a body lumen of a patient, various methods and devices may be implemented. The anchoring and securement devices may be delivered and positioned via an endoscopic apparatus that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and disposes one or more of the anchors through the tissue fold(s).

15 [0065] In securing the tissue folds or anchoring to or from these tissue folds or plications, over-compression of the tissue directly underlying the tissue anchors is preferably avoided. Over-compression of the underlying tissue may occur if the anchor compresses the tissue to such a degree that tissue necrosis or cutting of the underlying muscularis or serosal tissue by the anchor occurs. The anchor preferably  
20 exerts a force, e.g., about 0.1 - 0.5 lbs, sufficient to maintain or secure a tissue plication yet still allows for adequate blood flow to occur within the tissue underlying the anchor. Accordingly, the tissue anchor is preferably configured to accommodate a range of deflections due to various movements of the tissue due to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc., while maintaining  
25 or exerting a substantially constant force against the tissue.

[0066] Formation of a tissue fold may be accomplished using at least two tissue contact areas that are separated by a linear or curvilinear distance, wherein the separation distance between the tissue contact points affects the length and/or depth of the fold. In operation, a tissue grabbing assembly engages or grasps the tissue wall in  
30 its normal state (i.e., non-folded and substantially flat), thus providing a first tissue contact area. The first tissue contact area then is moved to a position proximal of a second tissue contact area to form the tissue fold. The tissue anchor assembly then may be extended across the tissue fold at the second tissue contact area. Optionally, a third tissue contact point may be established such that, upon formation of the tissue

fold, the second and third tissue contact areas are disposed on opposing sides of the tissue fold, thereby providing backside stabilization during extension of the anchor assembly across the tissue fold from the second tissue contact area.

**[0067]** The first tissue contact area may be utilized to engage and then stretch or rotate the tissue wall over the second tissue contact area to form the tissue fold.

The tissue fold may then be articulated to a position where a portion of the tissue fold overlies the second tissue contact area at an orientation that is substantially normal to the tissue fold. A tissue anchor may then be delivered across the tissue fold at or near the second tissue contact area. One apparatus which is particularly suited to deliver the anchoring and securement devices described herein may be seen in further detail in co-pending U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003, which is incorporated herein by reference in its entirety.

**[0068]** Various tissue anchors may be utilized for securing the tissue plications within the lumen. For instance, examples of tissue anchors which may be utilized are disclosed in co-pending U.S. Pat. App. Serial No. 10/612,170 filed July 1, 2003, which is incorporated herein by reference in its entirety. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different anchor types may be used in an anchor assembly. One particular type of anchor described herein is a reconfigurable "basket"-type anchor, which may generally comprise a number of configurable struts or legs extending between at least two collars or bushing members.

**[0069]** As described further below, an anchor may be adapted to exert a substantially constant force against a tissue surface, the anchor generally comprising a proximal collar, a distal collar, a plurality of deformable arms each extending between the proximal and distal collars, wherein the anchor is adapted to self-configure from a delivery configuration to an expanded configuration for placement against the tissue surface, and wherein the anchor is further adapted to exert a substantially constant force against the tissue surface over a range of deflections when the proximal and distal collars are moved relative to one another.

**[0070]** One particular illustrative basket anchor is shown in the perspective views of Figs. 1A and 1B. Fig. 1A shows deformable basket anchor **10** in a low-profile delivery configuration having proximal collar or bushing **14** and distal collar or bushing **16** with a plurality of struts or arms **12** extending between collars **14**, **16**. Each arm **12** may be separated from one another by spacing or opening **20**.

Moreover, each arm **12** may be aligned parallel with one another although this is not necessary. Anchor **10** may define lumen **18** through the length of anchor **10** to allow for the passage of one or more sutures therethrough.

[0071] Fig. 1B shows a perspective view of anchor **10** of Fig. 1A in an  
5 anchoring or expanded configuration **10'**. In such a configuration, proximal collar **14** and distal collar **16** are advanced towards one another such that the middle section **22** of arms **12** extend radially outwardly. Anchor **10'** may be made from various materials, e.g., spring stainless steel, but is preferably made from a shape memory or superelastic alloy, e.g., nitinol. The anchor may thus be shaped and heat-set such that  
10 it self-forms or automatically configures itself from the delivery configuration **10** to the expanded configuration **10'** upon release of a constraining force, e.g., when the anchor is ejected from its delivery needle or catheter, as described further below. Alternatively, the anchor may be configured to self-form into its expanded configuration **10'** upon the application of some activation energy to the anchor, e.g.,  
15 electrical energy, heat from the surrounding tissue, etc.

[0072] Upon expanding, the arms **12** of anchor **10'** may extend radially outwardly such that spacing or opening **20'** is defined between adjacent arms **12**. The spacing **20'** is preferably created to minimize the contact area between the anchor body and the underlying tissue surface to allow for greater blood flow in the tissue  
20 and to inhibit necrosis of the tissue.

[0073] When anchor **10'** contacts the tissue surface, proximal collar **14** and proximal section **24** of arm **12** lay against the tissue while distal section **26** of arm **12** extends away from the tissue surface. Although seven arms **12** are shown in this example, the number of arms is not intended to be limiting and may be varied, as  
25 described in further detail below. Moreover, the configurations of proximal **24**, distal **26**, and middle section **22** of arms **12** may also be varied and is also described in further detail below.

[0074] Deploying the anchors against, into, or through the tissue may be accomplished in a number of ways. One example is shown in Fig. 2A, which shows a  
30 cross-section of an anchor delivery system **30** in proximity to tissue fold **F**. Tissue fold **F** may comprise a plication of tissue created using any number of tissue plication devices. Examples of such devices which may be utilized are described in further detail in U.S. Pat. App. Serial No. 10/735,030 filed December 12, 2003. Tissue fold **F** may be disposed within a gastrointestinal lumen, such as the stomach, where tissue

wall **W** may define the outer or serosal layer of the stomach. The anchor delivery assembly may generally comprise launch tube **32** and needle **40** slidably disposed within the launch tube lumen. Needle **48** may generally be configured as a hollow needle having a tapered or sharpened distal end to facilitate its travel into and/or  
5 through the tissue.

[0075] Delivery push tube or catheter **34** may be disposed within launch tube **32** proximally of basket anchor **10**, which is shown in a compressed delivery configuration with a relatively low profile when disposed within needle lumen **42** of needle **40**. A single basket anchor **10** is shown disposed within needle **40** only for  
10 illustrative purposes and is not intended to be limited by the number of basket anchors; rather, any number of basket anchors may be disposed within needle lumen **42** as practicable depending upon the desired procedure and anchoring results.

[0076] Once launch tube **32** has been desirably positioned with respect to tissue fold **F**, needle **40** may be urged or pushed into or through tissue fold **F** via  
15 needle pushrod or member **44** from its proximal end. As shown in Fig. 2B, basket anchor **56** has been urged or ejected from needle **40** and is shown in its radially expanded profile for placement against the tissue surface. In such a case, a terminal end of suture **66** may be anchored within the distal collar of anchor **64** and routed through tissue fold **F** and through, or at least partially through, proximal anchor **56**,  
20 where suture **38** may be cinched or locked proximally of, within, or at proximal anchor **56** via any number of cinching or locking mechanisms **68**. Proximal anchor **56** is also shown in a radially expanded profile contacting tissue fold **F** along tissue contact region **54**. Locking or cinching of suture **38** proximally of proximal anchor **56** enables the adequate securement of tissue fold **F**.

[0077] A single suture or flexible element **38** (or multiple suture elements) may connect proximal anchor **56** and distal anchor **64** to one another through tissue fold **F** in the case of a single tissue fold **F**. If additional tissue folds are plicated for securement, distal anchor **46** may be disposed distally of at least one additional tissue fold **F'** while proximal anchor **56** may be disposed proximally of tissue fold **F**. As  
30 above, suture **38** may be similarly affixed within distal anchor **46** and routed through proximal anchor **56**, where suture **38** may be cinched or locked via cinching or locking mechanism **68**, as necessary. Locking mechanism **68** may be further configured to apply a locking force upon the suture **38** such that the anchors located upon both sides of tissue fold **F** (or tissue folds **F** and **F'**) may be advanced towards

one another while cinching the tissue plication(s). Suture or flexible element **38** may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, etc.

**[0078]** If tissue folds **F** and **F'** are to be positioned into apposition with one another, distal anchor **46** and proximal anchor **56** may be approximated towards one another. Proximal anchor **56** is preferably configured to allow suture **38** to pass freely therethrough during the anchor approximation. However, proximal anchor **56** is also preferably configured to prevent or inhibit the reverse translation of suture **38** through proximal anchor **56** by enabling uni-directional travel of anchor **56** over suture **38**. This cinching feature thereby allows for the automated locking of anchors **46**, **56** relative to one another during anchor approximation. Aspects of anchor positioning relative to tissue and various examples of cinching or locking mechanisms may be seen in further detail in U.S. Pat. App. Serial Nos. 10/840,950; 10/841,245; 10/840,951; and 10/841,411, each of which was filed May 7, 2004 and each being incorporated herein by reference in its entirety.

**[0079]** The anchors, as described above, may be seen in Fig. 2B to each have proximal collars **48**, **58** and respective distal collars **50**, **60** with struts or arms **52**, **62** extending therebetween. As described above, the basket anchors are preferably reconfigurable from a low profile delivery configuration to a radially expanded deployment configuration in which a number of struts, arms, or mesh elements may radially extend once released from launch tube **32** or needle **40**. Materials having shape memory or superelastic characteristics or which are biased to reconfigure when unconstrained are preferably used, e.g., spring stainless steels, Ni-Ti alloys such as Nitinol, etc.

**[0080]** The basket anchors are illustrated as having a number of reconfigurable struts or arm members extending between a distal collar and proximal collar; however, this is intended only to be illustrative and suitable basket anchors are not intended to be limited to baskets only having struts or arms, as will be described in further detail below. Examples of suitable anchors are further described in detail in the references which have been incorporated by reference above as well as in U.S. Pat. App. Serial No. 10/612,170 filed July 1, 2003, which is also incorporated herein by reference in its entirety.

**[0081]** As mentioned above, the anchor preferably exerts a force sufficient to maintain or secure a tissue plication yet still allows for adequate blood flow to occur

within the tissue underlying the anchor. When the anchor has been configured into its expanded configuration, a load or force may be applied to the anchor until the anchor has been optimally configured to accommodate a range of deflections while the anchor itself maintains or exerts a substantially constant force against the tissue.

5 Anchor deflection may occur, e.g., when the proximal and distal collars of an anchor have been advanced or urged towards one another such that the arms or struts extending therebetween are at least partially deflected. Moreover, anchor deflection may be due to various movements of the tissue attributable to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc.

10 **[0082]** Figs. 3A, 4A, and 5A illustrate an example of how the progressive deflection of an anchor may result in a substantially constant force exerted by the anchor itself. As shown in the graph 70 of Fig. 3A, an amount of anchor deflection,  $x$ , is plotted against the resulting force,  $F$ , exerted by the anchor. Fig. 3B shows an illustrative profile of an exemplary anchor; proximal collar 14, distal collar 16, and  
15 struts 12 are shown for reference. With proximal collar 14 stationary relative to the anchor, distal collar 16 may be urged initially at some distance,  $x$ . The anchor may thus be configured into an initial deflected configuration 72, as shown in Fig. 3B. The deflection may be induced via a suture or flexible member urging the collars towards one another, e.g., during tissue plication formation or securement.

20 **[0083]** Fig. 3A shows the corresponding increase in force 78 over the initial loading of the anchor through deflection,  $x$ . As the deflection of the anchor is increased, the anchor may be configured into a configuration 72', as shown in Fig. 4B, where the increasing force exerted by the anchor passes an inflection point 74 and enters an "optimal" window or range 80 in which the exerted force remains relatively  
25 constant over a range of deflections, as shown by the loading graph 70' in Fig. 4A. Within this range 80 of deflections, the amount of force exerted by the anchor may be substantially constant, i.e., relatively constant or increasing at a rate lower than the rate of initial loading 78 or rate of "over" loading 82 the anchor, as shown below.

**[0084]** At the upper portion of range 80, the force exerted by the anchor may  
30 begin to increase relative to the deflection, as indicated by loading curve 82 beyond inflection point 76 shown in the loading graph 70'' of Fig. 5A. Fig. 5B shows the corresponding over-loaded anchor configuration 72'' where the anchor may be seen as having been deflected beyond the configuration shown in Fig. 4B. The force representing the over loading of the anchor may increase steadily until the anchor is

forced into a configuration where proximal **14** and distal **16** collars have been urged towards one another to the point where they contact one another.

[0085] Knowing the anchor deflection-to-exerted force characteristics for a given anchor, one may load an anchor with a tension or compression force such that subsequent deflections of the underlying tissue being anchored occur within specified ranges, such as the optimal range. For instance, an anchor may be pre-loaded such that tissue fluctuations or movements occur within the optimal window or range where the force exerted by the anchor remains relatively constant over a range of deflections. This in turn may ensure that the underlying tissue is not subject to over-compression by the anchors.

[0086] One method for limiting the loading or pre-load force upon an anchor may involve including a post or stop **98** in the anchor body, as shown in the anchor variation **90** of Fig. 6A, which shows a partial cross-sectional view of the anchor. Post or stop **98** may be integrally formed with proximal collar **94** and extend distally between struts **92**. Alternatively, post **98** may also be fabricated separately and attached through one of a number of mechanical methods to proximal collar **94**, e.g., adhesives, threading, interference fitted, etc. Post **98** may define a lumen to allow suture **38** to pass through the anchor **90**. The anchor **90** may be loaded via suture **38** until the anchor **90** is configured to fall within the optimal window or range. As the underlying tissue moves, the anchor may be deflected accordingly; however, if the anchor is subjected to large deflections by the tissue, post **98** may prevent distal collar **96** of the anchor from over-compressing the anchor, as shown in the compressed configuration **90'** of Fig. 6B.

[0087] Another variation which may be utilized to limit the loading of the anchor during anchor placement and tensioning against the tissue is shown in the partial cross-sectional views of Figs. 7A and 7B. Tensioning assembly **100** may be seen proximally of anchor proximal collar **14** contained within the delivery push tube or catheter **102**. An elongate member **104**, e.g., a tubular member, may extend through catheter **102** and define a specified region **108** having a known coefficient of friction near or at the distal end of elongate member **104**. Frictional region **108** may be an area of the elongate member **104** having a separate material of known frictional coefficient coated or adhered thereon. Alternatively, the frictional region **108** may be integral with elongate member **104** and may simply be abraded or roughened to alter the frictional coefficient of region **108**.



[0088] Suture 38 may be attached at attachment point 106 to the distal end of elongate member 104 and may further extend into the anchor. As elongate member 104 is slid proximally through catheter 102 to impart a tension or load upon the anchor via suture 38, member 104 may pass through at least one or more regions which are in intimate contact around member 104. The regions in contact with member 104 may comprise at least a first frictional area 110 having a known first frictional coefficient. As elongate member 104 is withdrawn proximally in the direction of travel 118, frictional region 108 may slide against first frictional area 110 and generate a first frictional force I, as indicated by plot 120 on the graph of Fig. 8A. The generated first frictional force I may be detected through any number of various devices and may be used to indicate to the operator that anchor is being loaded.

[0089] As elongate member 104 is withdrawn further proximally, frictional region 108 may be withdrawn proximally of first frictional area 110 and against second frictional area 112, which may also have a known second frictional coefficient different from the first frictional coefficient of the first frictional area 110, as shown in Fig. 7B. A length of first frictional area 110 may accordingly be configured to correspond to the length of suture needed to load the anchor into its optimal configuration. As elongate member 104 slides against second frictional area 112, a second frictional force II may be generated which may be less than the first frictional force. Fig. 8B shows the drop in the generated frictional force as indicated by plot 122. This change in the detected force may thus be utilized to indicate to the operator that anchor has been configured within an optimal range of deflections. Once the anchor has been optimally configured, the suture may be secured relative to the anchor using any number of the cinching and/or locking methods as described in U.S. Pat. App. Serial Nos. 10/840,950; 10/841,245; 10/840,951; and 10/841,411, each being incorporated by reference above.

[0090] To prevent elongate member 104 from being over-withdrawn proximally and from over-compressing the anchor, protrusions 114 may project from elongate member 104 and corresponding stops 116 may project from within catheter 102. Protrusions 114 and the corresponding stops 116 may accordingly be configured to prevent the further withdrawal of elongate member 104 from catheter 102. Moreover, although first 110 and second 112 frictional areas are shown in this example, a single frictional area or additional areas may be utilized, each having a different coefficient of friction. Furthermore, first 110 and second 112 frictional areas

may be fabricated from different materials or they may be made from the same or similar material as catheter 102 and simply coated or covered with the various materials. For instance, first frictional area 110 may be fabricated from a material such as PEBAX®, while second frictional area 112 may be fabricated from a material such as HDPE. Alternatively, rather than utilizing a coating or covering, first 110 and second 112 frictional areas may be textured or abraded to create surfaces having differing frictional coefficients. The types of materials utilized or the types of surface textures created or even the number of different frictional areas are not intended to be limiting but are merely presented as possible variations. So long as a detectable change in the generated frictional force between elongate member 104 and the surrounding frictional region is created, any number of materials or regions may be utilized.

[0091] Fig. 9 shows another anchor tensioning variation in assembly 130. As shown, the tensioning assembly may be contained within delivery push tube or catheter 132. An elongate pull member 134, which may be manipulated via its proximal end by the user, may be connected to a tensioning block or member 136 via spring member 138. Pull member 134 and tensioning block or member 136 may generally be formed from a variety of biocompatible metals, e.g., stainless steel, Nitinol, etc., or plastics provided that the material is rigid relative to spring member 138 and suture 140 and will not affect the measurement of the linear deformation of spring member 138. Spring member 138 may generally comprise a linear spring element having a known spring constant. Suture 140 may be attached to a distal end of block 136 and further routed into or through distally located the tissue anchor.

[0092] During use in loading the tissue anchor, pull member 134 may be withdrawn proximally by its proximal end. As it is withdrawn, the force required to withdraw member 134 may be measured. With the spring constant and the measured force, the amount of linear deflection may be calculated to determine the amount of deflection the anchor has undergone. Alternatively, suture 140 may be marked uniformly at known distances with markings or gradations 142. As the pull member 134 is withdrawn, the length of suture 140 withdrawn into catheter 132 may be measured visually using, e.g., a video endoscope, by counting the number of gradations 142 passing into catheter 132. Knowing the linear distance and the spring constant, the anchor deflection may be calculated. Thus, measurement of either the force required to withdraw member 134 or the linear distance traveled by suture 140

may be utilized to determine the anchor deflection. With the known deflection, the assembly may be configured to indicate when the anchor has been deflected to a predetermined level, e.g., when the anchor has been deflected within the optimal range.

5     **[0093]**         Another alternative of an anchor tensioning assembly is shown in the partial cross-sectional view of Fig. 10. Assembly **150** may generally comprise an elongate pull member **152** connected to tensioning block or member **154**. Pull member **152** and tensioning block **154** may be fabricated from the same or similar materials as described above. A third element **156** having a known length which is  
10   less rigid than pull member **152** or tensioning block **154** may connect the two. This element **156** may have strain gauge **158** attached thereto for measuring the strain of the element **156** as pull member **152** is withdrawn proximally. The signals detected from the strain gauge **158** may be transmitted via wires **160** to a processor and/or display **162** located externally of the patient to record and process the strain  
15   information. With the known original length of element **156** and the measured strain, the length of linear deflection of the attached anchor may be calculated. With this information, the anchor deflection may be determined and the assembly **150** may be configured to indicate when the anchor has been deflected to a predetermined level to ensure optimal loading of the anchor.

20   **[0094]**         Yet another alternative is shown in the partial cross-sectional view of Fig. 11. In this variation, assembly **170** may simply comprise an anchor having a stepped proximal collar **172** to define a step or detent **174** which prevents the passage of stop member **176** contained within the anchor. The length of suture **38** extending from stop member **176** to the attachment point within the anchor may be of a  
25   predetermined length such that when stop member **176** is seated against proximal collar **172**, the suture length may compress the anchor into a predetermined deflection level. This deflection level may be preset to configure the anchor to any desired configuration, as described above.

**[0095]**         Yet another variation is shown in the partial cross-sectional views of  
30   Figs. 12A and 12B. Assembly **180** may generally comprise elongate pull member **152** and tensioning block or member **154**, as above. However, a fuse material **182**, i.e., a length of material having a preset or known failure or break strength, may be used to join pull member **152** and tensioning block **154**. This fuse **182** may generally comprise a variety of materials, e.g., silk, stainless steel, etc., provided that the failure

strength of fuse **182** is less than the force necessary for causing necrosis of the tissue to be anchored. For instance, a fuse **182** may be configured to break at a pressure of, e.g., 2 psi.

[0096] In operation, as elongate pull member **152** is withdrawn proximally, tensioning block **154** may be withdrawn as it is pulled by fuse **182**. As the anchor becomes compressed and the force on fuse **182** increases, once the force reaches the pre-set limit, the fuse **182** may break, as shown in Fig. 12B, thereby preventing further compression of the anchor and limiting the force applied onto the tissue.

[0097] Fuse **182** may be comprised from various materials. Optionally, the fuse may be altered to modify its break strength, e.g., by including multiple notches **192**, **194**, as seen in fuse variation **190** of Fig. 13A to create a necked-down region. Alternatively, a single notch **198** may be utilized, as seen in fuse variation **196**. The notches may be defined on the fuse to alter the break strength or to ensure the breakage or failure of the fuse.

[0098] When tensioning the anchors using any of the devices or methods described herein, various mechanisms may be used to apply the tensioning force on the suture. One mechanism is shown in the partial cross-sectional view of Fig. 14A, which shows a tensioning assembly **200** positioned within catheter **132**. The assembly may generally comprise tensioning mechanism **202**, which may have an anchor interface member **206** and a tensioning interface member **208** configured to slide relative to one another within catheter **132**. Anchor interface member **206** may define anchor collar channel **204** configured to receive and temporarily hold the proximal collar **14** of an anchor to be loaded.

[0099] Tensioning interface member **208** may be configured to slide relative to anchor interface member **206** via a slidable connection **210**. Tensioning member **208** may also comprise suture coupler **212** and hook **214** for holding terminal end **216** of suture **38** during a tensioning procedure. Tensioning member **208** and anchor member **206** may be urged towards one another via some biased member, e.g., spring member **218**, having a known spring constant. In use, when a tissue anchor is ready to be loaded, the proximal collar **14** may be held within anchor collar channel **204** and with terminal end **216** of suture **38** retained by hook **214**, tensioning member **208** may be withdrawn proximally relative to anchor member **206** until the desired tensioning level is reached. Other variations utilizing, e.g., a strain gauge, for measuring the

tension applied or utilizing, e.g., graspers, rather than a hook may be utilized to desirably tension the tissue anchors.

[0100] Fig. 14B shows a perspective view of an alternative tensioning assembly **201** which may be used to apply the load upon the anchor. This assembly **201** may be utilized in conjunction with any of the tension measuring apparatus described herein. As shown, anchor **10'** may be positioned at the distal end of base **205** with suture **38** extending proximally while being tensioned via suture coupler **212**, as in assembly **200** described above. Graspers **203**, which may be articulated to open or close, may be used to hold suture terminal end **216** while tensioning anchor **10'**. Base **205** may be configured to extend longitudinally, as above, or suture coupler **212** may be configured to slide proximally to tension the anchor **10'**.

[0101] Fig. 14C shows a device which may be used by the surgeon or operator outside a patient body to tension the anchors positioned within the body. Generally, the handle assembly may comprise handle **211** and a hollow elongate shaft **215** extending from the handle **211**. Shaft **215** may function much like a laparoscopic shaft if shaft **215** is rigid; alternatively, shaft **215** may be configured to be flexible for advancement within or through an endoscope or other working lumen, if so desired. A tensioning assembly, as described above, may be positioned within the lumen of shaft **215** near or at the distal end of shaft **215** and the control mechanisms, e.g., suture coupler **212**, may be actuatable from handle **211**. In one variation, control wheel or ratchet control **213**, which may be located on handle **211**, may be rotated in the direction of arrow **217** to actuate base **205** or suture coupler **212** in a proximal direction, as indicated by arrow **219**. Tensioning suture **38** with ratchet control **217** may draw anchors **207**, **209** towards one another to secure tissue fold **F** while also applying an appropriate load upon anchors **207**, **209**.

[0102] Various other factors of the tissue anchors may be modified to affect the tensioning and loading characteristics when deflecting the anchors. Moreover, some of the factors may also affect the interaction of the anchor with respect to the tissue in ensuring that the tissue is not over-compressed and that adequate blood flow may occur within the tissue directly beneath the anchor.

[0103] One factor may include varying the number of arms or struts of the anchor. For instance, the anchor may be configured to have, e.g., seven struts or arms **12** which deflect about the proximal **14** and distal **16** collars, as shown in the flattened view of one anchor variation **220** in Fig. 15A. Fig. 15B shows a side view of the

flattened anchor **220** while Fig. 15C shows a perspective view of the anchor **220** in an unexpanded delivery configuration.

[0104] Fig. 16A shows another variation of anchor **230** in a flattened view with struts or arms **232** extending between proximal collar **236** and distal collar **238**.

5 In this variation, five arms **232** may be utilized to increase the spacing **234** defined between adjacent arms **232**. The increased spacing **234** may be utilized to ensure the blood flow in the tissue beneath the tissue. Fig. 16B shows a side view of the flattened anchor **230** and Fig. 16C shows a perspective view of anchor **230** in its unexpanded delivery configuration. Other variations are discussed below.

10 [0105] Aside from varying the number of struts or arms, the configuration of the arms themselves may be varied. As seen in Fig. 16A, cross-sections of an individual arm **232** may be viewed for discussion purposes at three sections, proximal **I**, middle **II**, and distal **III** portions of the arm **232**. Figs. 17A to 17J show examples of possible variations for cross-sectional areas of an arm at each section, proximal **I**,  
15 middle **II**, and distal **III**. These figures are not intended to be limiting but are merely intended as examples of possible arm configurations.

[0106] Fig. 17A shows an arm configuration where sections **I** and **III** may be square in shape with the middle section **II** rectangular.

20 [0107] Fig. 17B shows an arm configuration where sections **I** and **III** may be rectangular in shape with the middle section **II** square.

[0108] Fig. 17C shows an arm configuration where sections **I** and **III** may be rectangular in shape in a transverse direction with the middle section **II** square.

[0109] Fig. 17D shows an arm configuration where sections **I** and **III** may be square in shape with the middle section **II** rectangular in a traverse direction.

25 [0110] Fig. 17E shows an arm configuration where all sections **I**, **II**, and **III** may be square in shape.

[0111] Fig. 17F shows an arm configuration where all sections **I**, **II**, and **III** may be rectangular in shape.

30 [0112] Fig. 17G shows an arm configuration where sections **I** and **III** may be circular in shape with the middle section **II** rectangular.

[0113] Fig. 17H shows an arm configuration where sections **I** and **III** may be elliptical in shape with the middle section **II** circular.

[0114] Fig. 17I shows an arm configuration where sections **I** and **III** may be circular in shape with the middle section **II** elliptical.

[0115] Fig. 17J shows an arm configuration where all sections **I**, **II**, and **III** may be circular in shape.

[0116] As mentioned above, varying the number of struts or arms may be utilized to vary not only the contact area with respect to the underlying tissue, but to also affect the optimal loading characteristics of the anchor. Aside from the number of arms, the positioning of the arms may also be utilized. For example, Figs. 18A to 18F show end views of anchor variations having a number of varying arms and arm positions. Again, these figures are not intended to be limiting but are merely intended as examples.

[0117] Fig. 18A shows the end view of an anchor **240** having 3 arms uniformly spaced apart.

[0118] Fig. 18B shows the end view of an anchor **242** having 4 arms uniformly spaced apart.

[0119] Fig. 18C shows the end view of an anchor **244** having 5 arms uniformly spaced apart.

[0120] Fig. 18D shows the end view of an anchor **246** having 6 arms uniformly spaced apart.

[0121] Fig. 18E shows the end view of an anchor **248** having 7 arms uniformly spaced apart.

[0122] Fig. 18F shows the end view of an anchor **250** having 9 arms uniformly spaced apart.

[0123] Any number of arms may be utilized as practicable and although the arms in the above examples are uniformly spaced apart from one another, the spacing between the arms may be varied irregularly or arbitrarily provided that the spacing between the arms enable adequate blood flow in the underlying tissue.

[0124] Not only can the number of arms and spacing between the arms be varied, but also the arm configurations themselves. For instance, the arms may be pre-formed into various shapes depending upon the desired effects on the anchor loading characteristics. As above, these figures are not intended to be limiting but are merely intended as examples.

[0125] Fig. 19A shows an illustrative side view of anchor **260** having curved arms.

[0126] Fig. 19B shows an illustrative side view of anchor **262** having circularly-shaped arms.

[0127] Fig. 19C shows an illustrative side view of anchor **264** having elliptically-shaped arms.

[0128] Fig. 19D shows an illustrative side view of anchor **266** having bow-shaped arms.

5 [0129] Fig. 19E shows an illustrative side view of anchor **268** having arms shaped into a figure-eight manner.

[0130] Fig. 19F shows an illustrative side view of anchor **270** having minimally-radiused arms.

10 [0131] Aside from the arm shapes, the length of the collars may be varied as well. Fig. 20A shows anchor variation **280** having extended anchor collars **282**, which may act to reduce the radius of the arms. Fig. 20B shows anchor variation **284** having reduced collars **286**, which may act to increase the radius of the arms. As above, these figures are not intended to be limiting but are merely intended as examples.

15 [0132] When the anchors are deployed into or against the tissue, at least one portion of the anchor arms are generally against the tissue surface while another portion of the arms are exposed within the lumen. The exposed portions of the anchor may be optionally coated or covered with a material to protect against exposure to foreign materials, e.g., food or other object which may be ingested by the patient,  
20 other surgical tools, etc. Accordingly, as shown in the perspective view of anchor variation **290** in Fig. 21A, biocompatible coating or covering **292** may be placed over the entire length of the anchor arms **12** or only along the portions of the arms **12** not against the tissue. The coating or covering **292** may be comprised from various materials, e.g., elastomers, plastics, etc.

25 [0133] Alternatively, a mesh or skirt-like covering **298** may be placed over the exposed portion of the anchor **294**, as shown in Fig. 21B, which is attached to the anchor via attachment points **298** along each of some of the arms **12**. Yet another alternative may be seen in anchor variation **300** in Fig. 21C in which the entire anchor itself may be covered with a distensible or expandable covering or mesh.

30 [0134] In yet another variation shown in Fig. 22A, a combination hybrid basket assembly **310** may generally comprise basket anchor **10**, as previously described, which may be placed entirely within a basket anchor **312** comprised primarily of a mesh or distensible material, e.g., PTFE, PET, etc. Each anchor, i.e., basket anchor **10** and mesh anchor **312**, may each be formed individually and basket



anchor **10** may be positioned through mesh basket opening **320** such that basket anchor **10** is entirely enveloped by mesh **318** within mesh basket **312**. Mesh basket **312** may be comprised generally of a mesh **318** having proximal **314** and distal **316** collars, as shown. Moreover, mesh **318** may be pre-formed to expand from a low profile configuration for delivery into an expanded configuration for deployment.

[0135] When deployed for tissue securement, one or more hybrid basket assemblies, e.g., first basket assembly **310A** and second basket assembly **310B** as shown in Fig. 22B, may be interconnected via suture **38** such that suture **38** passes freely through one or both basket assemblies **310A**, **310B**.

[0136] Generally, basket anchor **10** may freely float within mesh basket **312** such that the proximal **14** and distal **16** collars of basket anchor **10** are freely moveable with respect to proximal **314** and distal **316** collars of mesh basket **312**, as shown and described above. Alternatively, one or both ends of the anchor collars may be fused or formed to one another. For example, as shown in Fig. 23A, basket assembly **310** may be seen with detail views of either collar ends. In this example, distal collar **16** of basket anchor **10** may freely move, as shown by arrow **332**, with respect to distal collar **316** of mesh basket **312** through mesh basket opening **320** at free-anchor end **336**. Distal collar **316** may also freely move, as shown by arrows **330**. The proximal collar **14** of basket anchor **10**, on the other hand, may be fused, formed, welded, adhered, or otherwise attached to proximal collar **314** of mesh basket **312** at fused-anchor end **334** such that relative movement between the collars **14**, **314** is prohibited or restrained.

[0137] Thus, when proximal collars **14**, **314** at fused-anchor end **334** are placed against a tissue surface to be secured, distal collars **16**, **316** at free-anchor end **336** may freely translate with respect to one another such that anchor assembly **310** may be fully cinched or compressed freely without any mismatched compression occurring between basket anchor **10** and mesh anchor **312**. Alternatively, distal collars **16**, **316** may also be fused or attached to one another such that movement of either collar ends are fully constrained with respect to each anchor. In such an alternative, the compression rate of basket anchor **10** is preferably matched with that of mesh anchor **312**.

[0138] An example of use for the fused hybrid anchors is shown in Fig. 23B. A distal hybrid anchor **310** having a basket anchor enclosed within mesh **318** may be deployed on a first side of a tissue region to be plicated, e.g., into a tissue fold **F**, as

described above. The proximal collars **14**, **314** of the hybrid anchor assembly **310** may be deployed such that fused-anchor end **334** rests against or abuts the surface of the tissue. With suture **38** passing through distal hybrid anchor **310** and through the dual-layers of tissue fold **F**, a proximal hybrid anchor **310'**, likewise having a basket anchor enclosed within mesh **318'**, may be deployed on a proximal side of the tissue fold **F** such that its proximal collars of fused-anchor end **334'** rests against or abuts the surface of the tissue, also as described above. Suture **38** may also pass from the tissue fold **F** and through the proximal hybrid anchor **310'**.

[0139] As the hybrid anchors **310**, **310'** are approximated towards one another by tensioning suture **38**, the tissue is formed into a serosa-to-serosa contacting tissue fold **F**, as shown in Fig. 23C. As the hybrid anchors **310**, **310'** are further cinched towards one another, the free-floating collars **16**, **16'** of their respective free-anchor ends **336**, **336'** may freely move while the respective fused-anchor ends **334**, **334'** may each lie against the surface of tissue fold **F**. Thus, having the translating free-anchor ends **336**, **336'** of the apposed basket anchors positioned away from the plicated tissue while having the fused-anchor ends **334**, **334'** placed against the plicated tissue may ensure smooth anchor compression and cinching of the tissue.

[0140] In another variation, Fig. 24A illustrates a side view of another hybrid basket assembly **340** having a mesh anchor **312** with a basket anchor contained within having arm members or struts **342** which are formed in a curved, spiraled, or arcuate shape between collars **14**, **16**. When compressed for securing tissue, mesh anchor **312** may compress into its disk-shaped configuration, but curved or spiraled arm members **342** may compress into a looped, spiraled, or flower-shaped configuration, as shown in the top compressed view of Fig. 24B. Such a spiraled configuration may allow for compression of the basket anchor within the mesh anchor **312** while retaining a smooth or atraumatic outer diameter with respect to an inner surface of the mesh **318** when compressed.

[0141] In yet another variation, compressible anchor **350** may be comprised generally of a mesh **356**, as described above, which is pre-formed to compress into a double-disk configuration. Fig. 25A shows a low-profile configuration of the anchor **350** having one or more radially-biased bulges **352** pre-formed between at least one inwardly-biased radius **354**. When compressed, as shown in Fig. 25B, radially-biased bulges **352** may each flatten radially into a disk-shaped configuration adjacently formed with respect to one another while inwardly-biased radius **354** is biased to

flatten in an opposite direction. As shown in the top compressed view in Fig. 25C, bulges 352 may essentially form hardened circumferential rings of flattened mesh 356 which further inhibit or prevent the tissue anchors from being pulled through the secured tissue. Although compressible anchor 350 is shown as a mesh basket, a  
5 basket anchor may also be placed therewithin, if so desired.

[0142] In a further variation, an additional ring, band, or other structure may be integrated with the anchor of Figs. 25A to 25C to facilitate the formation of the circumferential rings when the anchor is flattened. For instance, Figs. 26A and 26B show compressible anchor 360 having the ring, band, or other retaining structure 362  
10 formed at or along inwardly-biased radius 354. This structure 362 may be integrally formed with mesh 356 by an adhesive or other mechanism. Structure 362 may be formed into, e.g., a circular or elliptical ring or band, made of any number of non-distensible or partially distensible polymeric or elastomeric materials, e.g., PTFE, silicon, urethane, etc., or any number of other metals or alloys, e.g., Nitinol, stainless  
15 steel, etc. When the anchor 360 expands from its low-profile configuration, as shown in Fig. 26A, the structure 362 may retain the portion of mesh 356 around radius 354 such that when the anchor 360 is flattened against the tissue surface, the bulges 352 may more easily flatten into their expanded configurations about radius 354, as shown in Fig. 26B.

20 [0143] Figs. 27A to 27C show yet another variation of the anchors which may include a biasing element therewithin to facilitate reconfiguration of the anchor from a low-profile deployment configuration to at least a partially expanded configuration. As illustrated in Fig. 27A, the anchor assembly 370 is configured as above with proximal 314 and distal 316 collars with mesh 318 connected between the two. A  
25 biasing element, such as a spring element 372, may be disposed within mesh 318 and connected to both collars 314, 316 at either end of spring element 372. Although shown as a spring in this example, the biasing element may alternatively be configured as various mechanisms such as an elastic band or element connected at either end to collars 314, 316. The spring element 372 is generally biased to urge  
30 collars 314, 316 towards one another, as indicated by the arrows in the figure, such that when anchor assembly 370 is free of the constraints of being contained within a needle body during delivery, collars 314, 316 are drawn towards one another to automatically urge mesh 318 into at least a partially reconfigured shape, as shown in Fig. 27B. Fig. 27C shows the anchor assembly of Fig. 27B with the mesh 318

partially removed only for clarity. As seen, collars 314, 316 have been drawn towards one another by spring element 372 such that mesh 318 has conformed at least partially into an expanded shape.

[0144] Spring element 372 may be a separate spring which is attached, e.g.,  
5 via welding, adhesive, crimping, or other attachment mechanisms, etc., to collars 314, 316. However, in other alternatives, spring element 372 and collars 314, 316 may comprise an integral continuous structure. For instance, collars 314, 316 may be formed by winding the terminal ends of spring element 372 into closely wound coils or partial coils. Mesh 318 may be otherwise attached to the coil-formed collars 314,  
10 316. Furthermore, spring element 372 may be made from a variety of metal, metal alloy, polymeric material, or combinations thereof. Examples of such metals and metal alloys may include, but are not limited to, stainless steel, nickel, titanium, nitinol, etc. while some examples of polymeric materials may include, but are not limited to, plastic, elastomers, polyurethane, salastic materials, etc.

15 [0145] Having spring element 372 urge the collars 314, 316 towards one another facilitates the complete expansion of the mesh 318 against a tissue surface when suture 38 is pulled or tensioned to draw the anchor against the tissue surface by inhibiting the anchor from inadvertently being pulled through a tissue surface. As spring element 372 is positioned through a central axis between collars 314, 316,  
20 suture 38 may be passed through the center of spring 372 such that anchor assembly 370 slides freely over suture 38. Alternatively, a terminal end of suture 38 may be secured against or attached to one of the collars 314, 316.

[0146] Fig. 28A illustrates the anchor assembly of Figs. 25A to 25C with the addition of spring element 372 disposed within mesh 356 and attached at either end to  
25 collars 314, 316. As described above, mesh 356 of the compressible anchor may be pre-formed to compress into a double-disk configuration. The low-profile delivery configuration is shown in Fig. 28A as having one or more radially-biased bulges 352 pre-formed between at least one inwardly-biased radius 354. With spring element 372 disposed within mesh 356 and attached to collars 314, 316, the anchor may be  
30 urged to reconfigure itself into at least a partially expanded and compressed configuration where the radially-biased bulges 352 may each partially flatten radially into a disk-shaped configuration adjacently formed with respect to one another while inwardly-biased radius 354 is biased to at least partially flatten in the opposite direction, as shown in Fig. 28B. Fig. 28C shows the anchor assembly of Fig. 28B

with the mesh 356 partially removed only for clarity. As seen, collars 314, 316 have been drawn towards one another by spring element 372 such that mesh 356 has conformed at least partially into its double-disk configuration. Suture 38 may also be seen as being slidably disposed through spring element 372. As above, spring  
5 element 372 may comprise a separate biased element which is attached or connected between the collars 314, 316. Alternatively, collars 314, 316 may also be formed by winding the terminal ends of spring element 372 into closely wound coils or partial coils to form a continuous structure.

[0147] Although spring elements 372 are shown as partially approximating  
10 the collars 314, 316 toward one another to result in a partially expanded mesh 356, spring elements 372 having a relatively higher spring force may alternatively be used. Use of a spring element having a high spring force may result in an anchor where once such an anchor is unconstrained, the collars 314, 316 may be drawn as closely together as practicable by the spring element 372 such that mesh 356 is fully  
15 reconfigured into a completely expanded configuration.

[0148] Fig. 29 illustrates the anchor of Fig. 28 in its low-profile delivery configuration disposed within needle lumen 42 of delivery needle 40. As shown, a first mesh anchor 374A is positioned within needle lumen 42 distally of second mesh anchor 374B. Each anchor 374A, 374B is shown in cross-section with mesh 356  
20 partially removed for clarity to illustrate spring elements 372 disposed within each respective anchor 374A, 374B attached to both collars. When anchor 374A, 374B are constrained in their low-profile configuration, spring elements 372 may be under tension and are biased to pull or draw their respective collars towards one another. Suture 38 may be seen passing through each respective spring element 372 through  
25 each anchor 374A, 374B.

[0149] After first anchor 374A is ejected from needle 40 on a first respective side of tissue fold F, second anchor 374B may be ejected from needle 40 on a second respective side of tissue fold F in one example of securing a tissue fold F, as shown in Fig. 30A and as described above. As shown, once anchors 374A, 374B have been  
30 deployed and are free from the constraints of being contained within needle lumen 42, the collars are free to move towards one another under the force of spring elements 372 over suture 38. The resulting configuration of the mesh 356 may be seen as being at least partially expanded under the biased spring force from spring elements 372. Moreover, because of the biasing force from the elastic element or spring element

372, the mesh 356 is urged to reconfigure itself into its partially expanded shape. Accordingly, as the anchors 374A, 374B are pushed distally through needle lumen 42, the anchors 374A, 374B themselves facilitate automatic reconfiguration into a “popped-open” shape.

5 [0150] With anchor 374A, 374B at least partially expanded, when suture 38 is pulled or tensioned to draw anchors 374A, 374B towards one another to secure tissue fold F into its plicated configuration, the anchors 374A, 374B are inhibited from collapsing back into their low-profile configuration by spring elements 372 and being pulled through the tissue fold F. Rather, because anchors 374A, 374B are already  
10 partially expanded, when suture 38 is tensioned, anchors 374A, 374B may naturally assume their fully expanded configuration against the tissue fold F, further inhibiting anchors 374A, 374B from being pulled through, as shown in Fig. 30B.

[0151] Although the examples above illustrate anchors 374A, 374B used to secure a single tissue fold F, the anchor assemblies described above may be utilized in  
15 any number of procedures and in various regions of the body. For instance, anchors 374A, 374B may be used not only to hold tissue folds but also to join one or more tissue layers, or also to approximate one or more tissue edges and tissue openings which may have been created surgically or otherwise present naturally in the patient body.

20 [0152] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Any of the modifications to an anchor, e.g., number of arms, arm configuration, cross-sectional variations, anchor collar length, coatings or coverings over the anchor, etc., may be  
25 done in a variety of combinations with one another. For instance, depending upon the desired loading characteristics, an anchor may be made having a number of arms with various cross-sectional areas along one or more of the arm lengths and may additionally have one or both collars varied in length.

[0153] Any of the combinations or modifications is intended to be within the  
30 scope of this invention. Moreover, although configurations may be shown with various types of anchors, it is intended that the various configurations be utilized in various combinations as practicable. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

## CLAIMS

What is claimed is:

1. An anchor assembly for securing tissue, comprising:  
a compressible basket anchor having a first proximal collar, a first distal  
5 collar, and a plurality of deformable arms each extending between the first proximal  
and first distal collars; and  
a mesh anchor having a second proximal collar, a second distal collar, and a  
deformable mesh surface extending between the second proximal and distal collars,  
wherein the basket anchor is disposed within the mesh anchor such that the  
10 first and second proximal collars are adjacent to one another and the first and second  
distal collars are adjacent to one another.
2. The anchor assembly of claim 1 wherein the anchor assembly is adapted to  
self-configure from a delivery configuration to an expanded configuration for  
15 placement against a tissue surface.
3. The anchor assembly of claim 1 wherein the plurality of deformable arms  
extend in an arcuate or spiral configuration between the first proximal and first distal  
collars.  
20
4. The anchor assembly of claim 1 wherein the compressible basket anchor is  
comprised of a shape memory alloy.
5. The anchor assembly of claim 1 wherein the first proximal collar and  
25 second proximal collar are attached to one another.
6. The anchor assembly of claim 5 wherein the first distal collar and second  
distal collar are attached to one another.
- 30 7. The anchor assembly of claim 1 further comprising a length of suture  
routed through the anchor assembly.
8. The anchor assembly of claim 1 wherein the basket anchor and mesh  
anchor are freely movable relative to one another.

9. An anchor for securing tissue, comprising:  
a proximal collar;  
a distal collar; and  
5 a mesh surface extending between the proximal and distal collars,  
wherein the mesh surface is pre-formed to have one or more radially-biased  
bulges such that compression of the mesh surface from a delivery configuration to a  
securement configuration forms a circumferential ring which inhibits passage of the  
anchor through a tissue surface.
- 10 10. The anchor of claim 9 further comprising a basket anchor disposed within  
the mesh surface.
11. The anchor of claim 9 further comprising a length of suture routed  
15 through the proximal and distal collars.
12. The anchor of claim 9 wherein the mesh surface is pre-formed to have at  
least two radially-biased bulges.
- 20 13. The anchor of claim 12 wherein the mesh surface is further pre-formed to  
have at least one inwardly biased portion between the two radially-biased bulges.
14. The anchor of claim 13 where the inwardly biased portion is adapted to  
form a first diameter which is less than a second diameter of the two radially-biased  
25 bulges.
15. The anchor of claim 13 further comprising a ring or band formed at or  
about the inwardly biased portion for facilitating formation of the circumferential  
ring.
- 30 16. An anchor for securing tissue, comprising:  
a proximal collar;  
a distal collar;



a biased element connected to the proximal and distal collars and which is adapted to urge the collars toward one another; and  
a mesh surface extending between the proximal and distal collars.

5           17. The anchor of claim 16 wherein the mesh surface is pre-formed to have one or more radially-biased bulges such that compression of the mesh surface from a delivery configuration to a securement configuration forms a circumferential ring which inhibits passage of the anchor through a tissue surface.

10           18. The anchor of claim 17 wherein the mesh surface is pre-formed to have at least two radially-biased bulges.

            19. The anchor of claim 18 wherein the mesh surface is further pre-formed to have at least one inwardly biased portion between the two radially-biased bulges.

15           20. The anchor of claim 19 where the inwardly biased portion is adapted to form a first diameter which is less than a second diameter of the two radially-biased bulges.

20           21. The anchor of claim 19 further comprising a ring or band formed at or about the inwardly biased portion for facilitating formation of the circumferential ring.

            22. The anchor of claim 16 wherein the biased element comprises a spring.

25           23. The anchor of claim 22 wherein the spring extends between the proximal and distal collars within the mesh surface.

            24. The anchor of claim 22 wherein the spring is comprised of a metal, metal alloy, polymeric material, or combination thereof.

30           25. The anchor of claim 24 wherein the spring is comprised of a material selected from the group consisting of stainless steel, nickel, titanium, nitinol, plastic, elastomers, polyurethane, and salastic materials.

26. The anchor of claim 16 further comprising a basket anchor disposed within the mesh surface.

5        27. The anchor of claim 16 further comprising a length of suture routed through the proximal and distal collars.

28. The anchor of claim 16 wherein the proximal and distal collars are formed from the terminal ends of the biased element such that the proximal and distal collars  
10        and the biased element form a continuous structure.

29. An anchoring system for securing tissue, comprising:  
a proximal collar;  
a distal collar;  
15        a spring element connected to the proximal and distal collars and which is adapted to urge the collars toward one another;  
a mesh surface extending between the proximal and distal collars and surrounding the spring element; and  
a length of suture passing through each collar and through the spring element.

20        30. The system of claim 29 wherein the mesh surface is pre-formed to have one or more radially-biased bulges such that compression of the mesh surface from a delivery configuration to a securement configuration forms a circumferential ring which inhibits passage of the anchor through a tissue surface.

25        31. The system of claim 30 wherein the mesh surface is pre-formed to have at least two radially-biased bulges.

32. The system of claim 31 wherein the mesh surface is further pre-formed to  
30        have at least one inwardly biased portion between the two radially-biased bulges.

33. The system of claim 32 where the inwardly biased portion is adapted to form a first diameter which is less than a second diameter of the two radially-biased bulges.

34. The system of claim 32 further comprising a ring or band formed at or about the inwardly biased portion for facilitating formation of the circumferential ring.

5

35. The system of claim 29 further comprising a needle catheter having a lumen defined therethrough within which each of the collars, spring element, and mesh surface is positionable.

10

36. The anchor of claim 29 wherein the proximal and distal collars are formed from the terminal ends of the biased element such that the proximal and distal collars and the biased element form a continuous structure.

15

37. A tissue anchor system for securing tissue, comprising:

a first tissue anchor having a first proximal collar, a first distal collar, a first biased element connected to the proximal and distal collars and which is adapted to urge the collars toward one another, and a first mesh surface extending between the proximal and distal collars;

20

a second tissue anchor having a second proximal collar, a second distal collar, a second biased element connected to the proximal and distal collars and which is adapted to urge the collars toward one another, and a second mesh surface extending between the proximal and distal collars;

25

a length of suture passing through the first and second tissue anchors such that a terminal end of the suture is disposed distally of or attached to the first tissue anchor; and

a locking mechanism slidably disposed along the length of suture at a position proximally of or attached to the second tissue anchor.

30

38. The system of claim 37 wherein at least one of the first mesh surface and the second mesh surface is pre-formed to have one or more radially-biased bulges such that compression of the first and/or second mesh surfaces from a delivery configuration to a securement configuration forms a circumferential ring which inhibits passage of the first and/or second tissue anchor through a tissue surface.

39. The system of claim 38 wherein at least one of the first mesh surface and the second mesh surface is pre-formed to have at least two radially-biased bulges.

40. The system of claim 39 wherein at least one of the first mesh surface and the second mesh surface is further pre-formed to have at least one inwardly biased portion between the two radially-biased bulges.

41. The system of claim 37 wherein at least one of the first biased element and the second biased element comprises a spring.

42. The system of claim 41 wherein the spring extends between the first proximal and distal collars.

43. The system of claim 41 wherein the spring extends between the second proximal and distal collars.

44. The system of claim 37 wherein the first proximal and distal collars are formed from the terminal ends of the first biased element such that the first proximal and distal collars and the first biased element form a continuous structure.

45. The system of claim 44 wherein the second proximal and distal collars are formed from the terminal ends of the second biased element such that the second proximal and distal collars and the second biased element form a continuous structure.

46. The system of claim 37 wherein the terminal end of the suture comprises a knot or projection which is inhibited from passing through the first tissue anchor.

47. The system of claim 37 wherein the length of suture passes through the first biased element of the first tissue anchor and the second biased element of the second tissue anchor.

48. The system of claim 37 wherein the locking mechanism comprises a cinch adapted to slide uni-directionally along the length of suture towards the second tissue anchor.

49. A method of deploying a tissue anchor, comprising:

delivering a tissue anchor having a proximal collar, a distal collar, and a mesh surface having a low-profile configuration extending between the collars;

5        deploying the tissue anchor against a tissue surface such that the distal and proximal collars are approximated at least partially towards one another via a spring element connected therebetween and wherein the mesh surface conforms to a partially expanded configuration; and

10        tensioning a length of suture between the distal and proximal collars to further expand the mesh surface into a fully deployed configuration against the tissue surface.

50. The method of claim 49 wherein delivering comprises passing a needle body through at least one tissue fold.

15        51. The method of claim 49 wherein deploying comprises ejecting the tissue anchor from a needle body.

52. The method of claim 51 wherein deploying comprises ejecting at least two tissue anchors from the needle body.

20        53. The method of claim 49 wherein deploying comprises conforming the mesh surface to a partially expanded configuration having one or more radially-biased bulges where compression of the mesh surface forms a circumferential ring.

25        54. The method of claim 53 wherein conforming the mesh surface comprises partially expanding the mesh surface having at least two radially-biased bulges.

55. The method of claim 49 wherein prior to tensioning a length, further comprising:

30        delivering a second tissue anchor having a second proximal collar, a second distal collar, and a second mesh surface having a low-profile configuration extending between the collars; and

deploying the second tissue anchor against a second tissue surface such that the second distal and proximal collars are approximated at least partially towards one

another via a second spring element connected therebetween and where the second mesh surface conforms to a partially expanded configuration.

5        56. The method of claim 55 wherein the second tissue surface is located on a tissue fold opposite to the tissue surface.

57. The method of claim 55 wherein the second tissue surface is located on a tissue fold separate from the tissue surface.

10        58. The method of claim 55 wherein the second tissue surface is located along an edge of a tissue opening in apposition to the tissue surface.

59. The method of claim 58 wherein the tissue opening is surgically created.

15        60. The method of claim 58 wherein the tissue opening is naturally occurring.

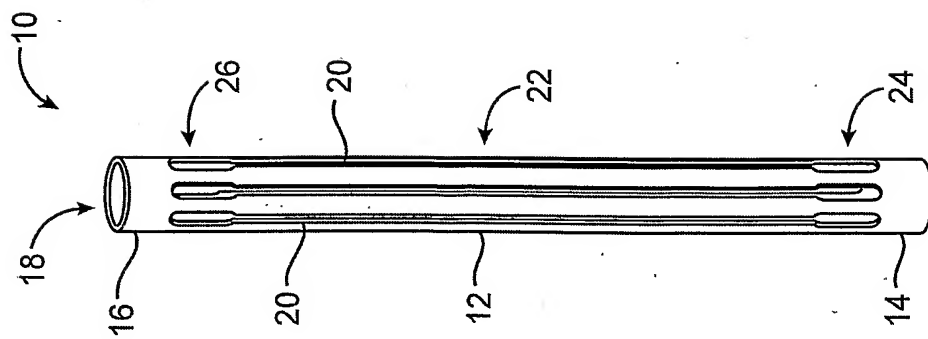


FIG. 1A

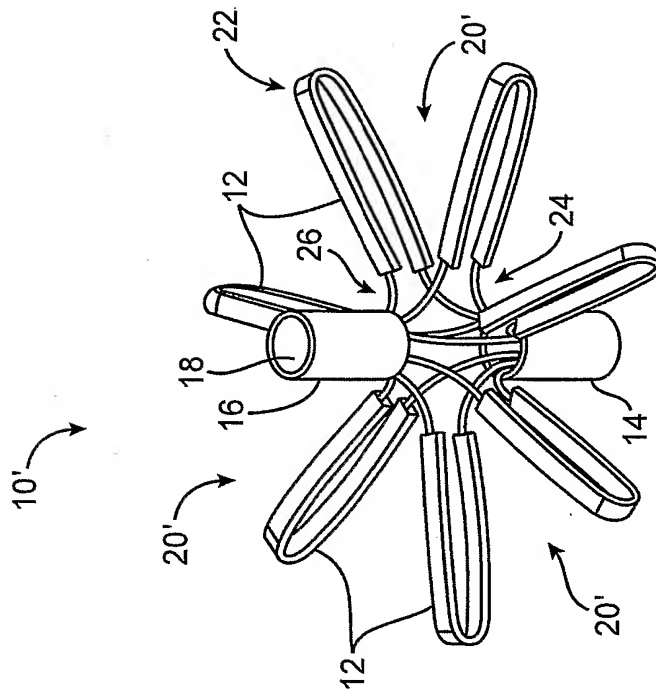


FIG. 1B

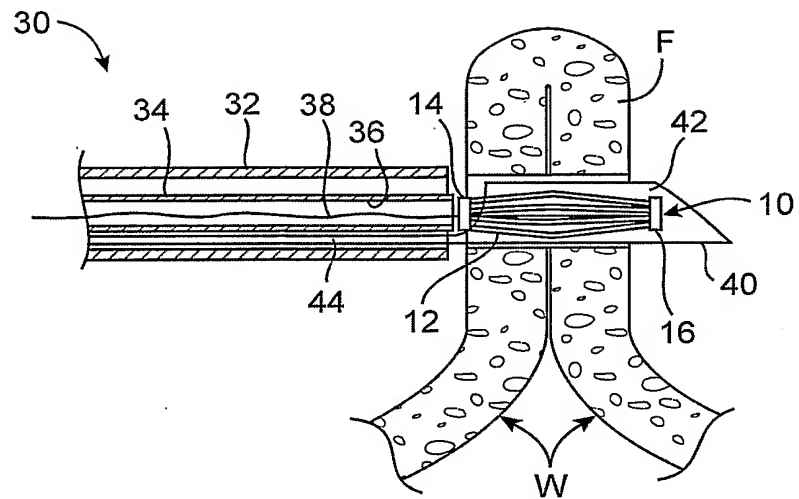


FIG. 2A

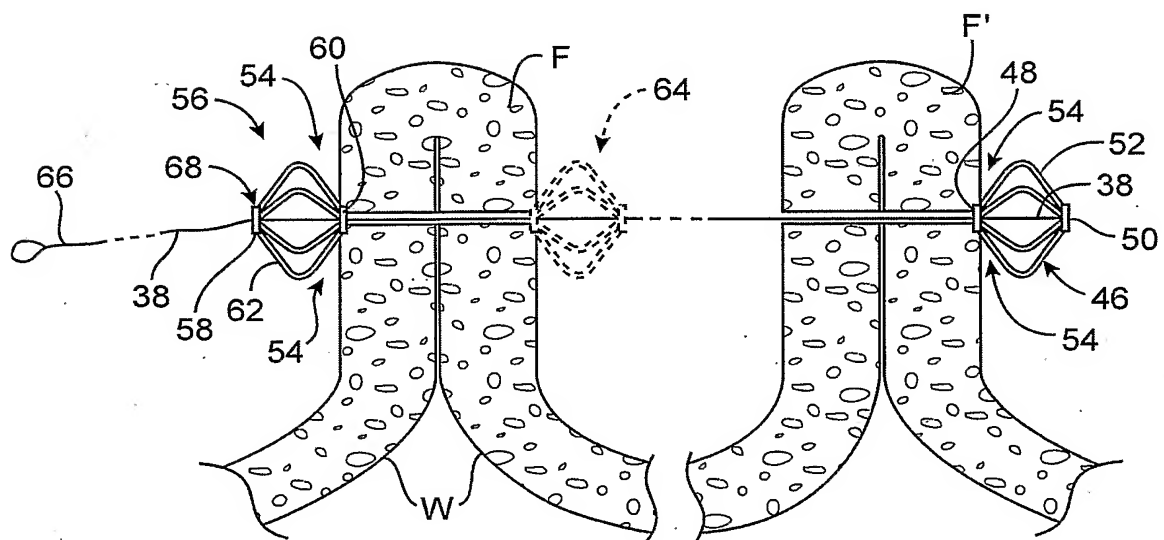


FIG. 2B



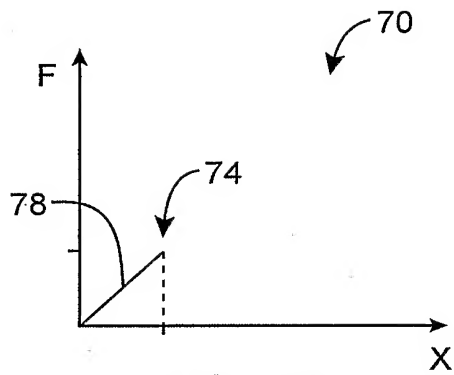


FIG. 3A

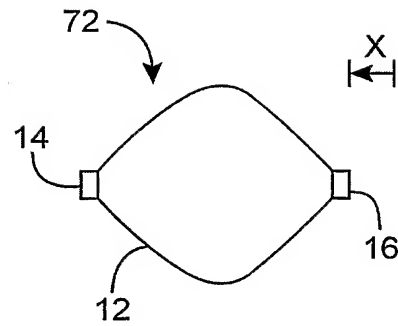


FIG. 3B

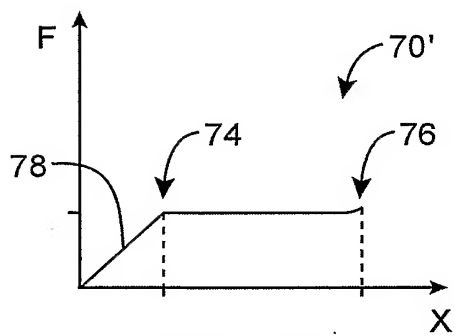


FIG. 4A

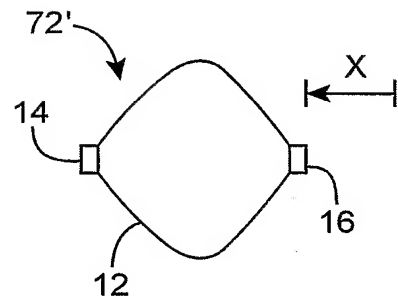


FIG. 4B

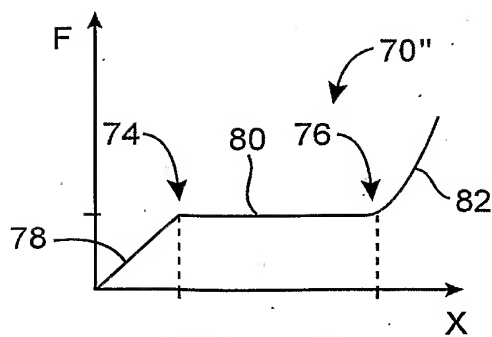


FIG. 5A

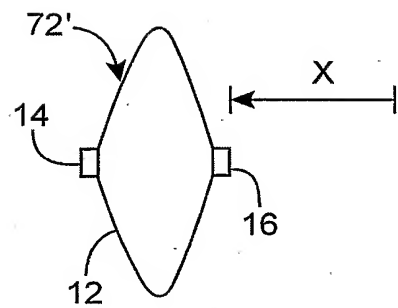


FIG. 5B

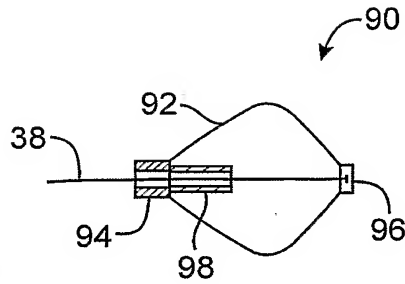


FIG. 6A

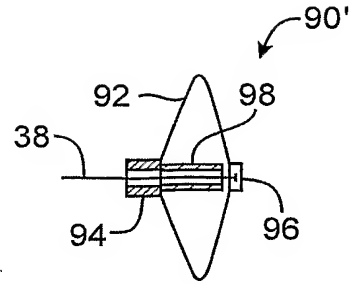


FIG. 6B

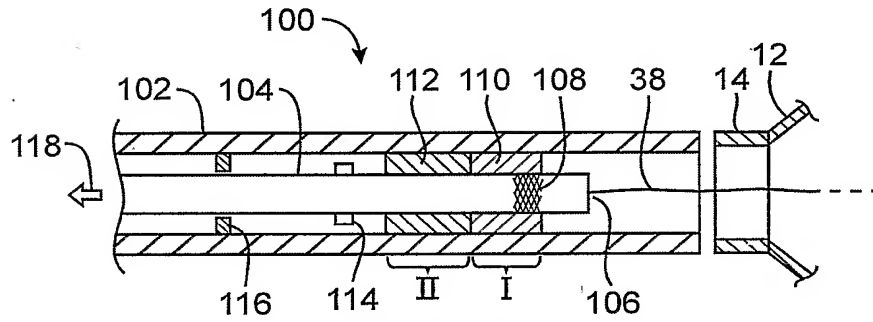


FIG. 7A

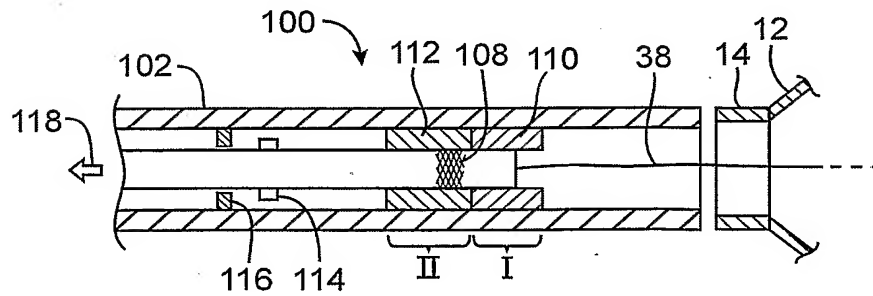


FIG. 7B

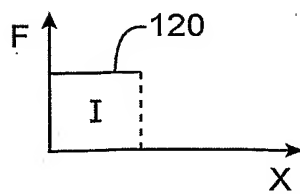


FIG. 8A

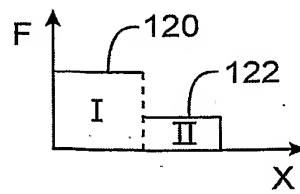


FIG. 8B

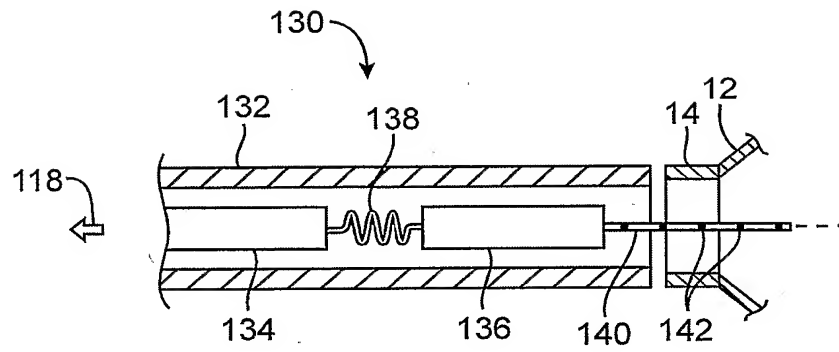


FIG. 9

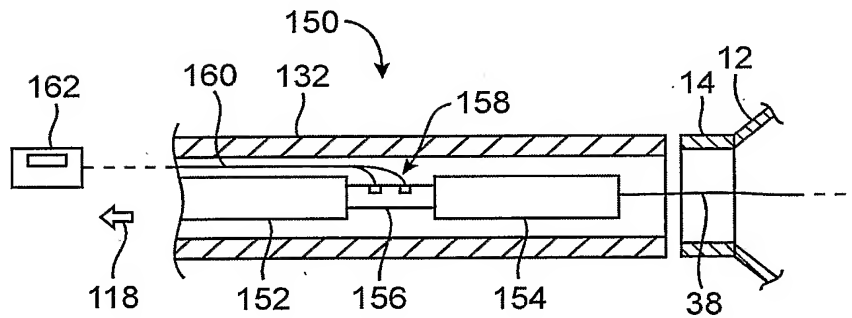


FIG. 10

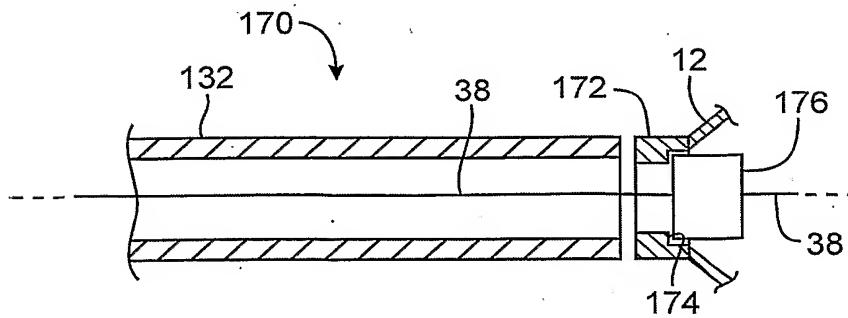


FIG. 11

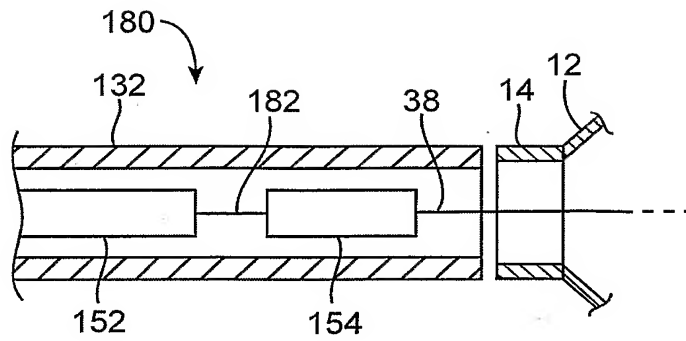


FIG. 12A

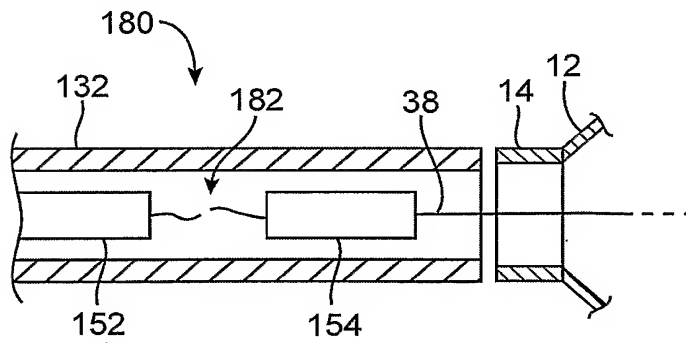


FIG. 12B

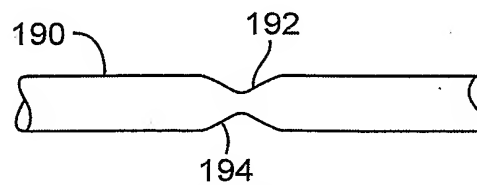


FIG. 13A

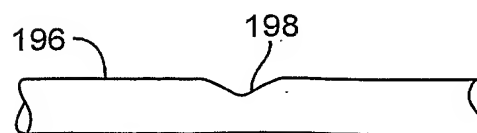


FIG. 13B

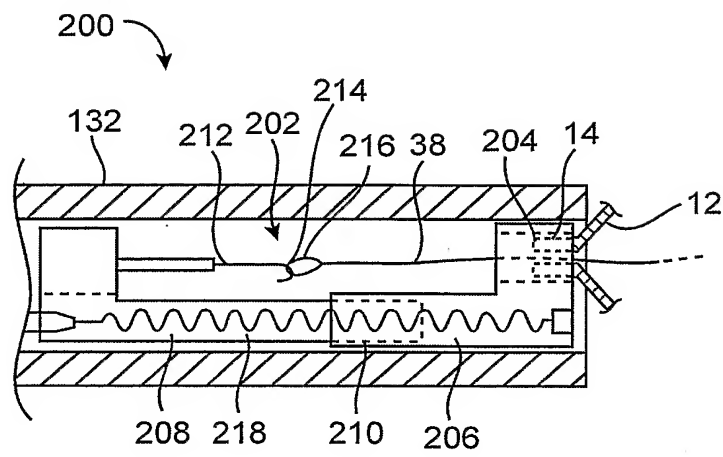


FIG. 14A

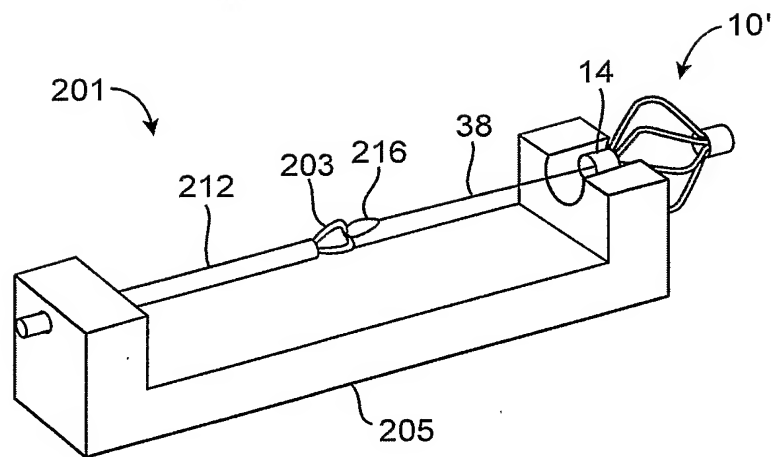


FIG. 14B

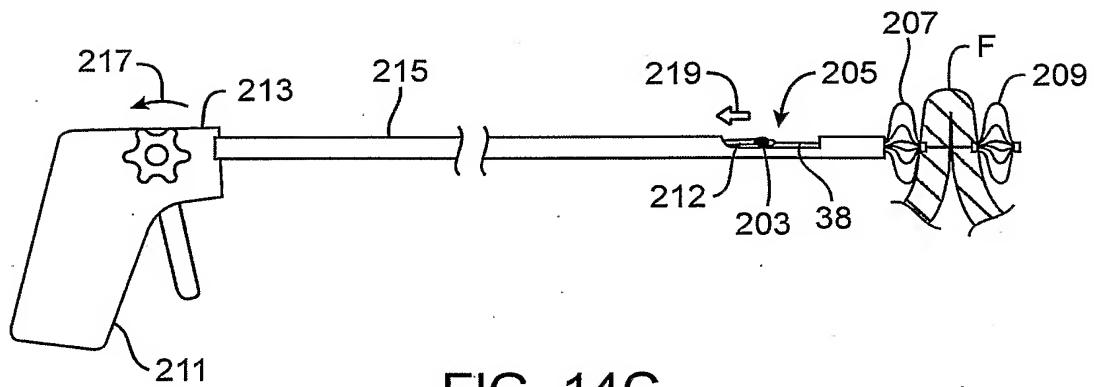


FIG. 14C

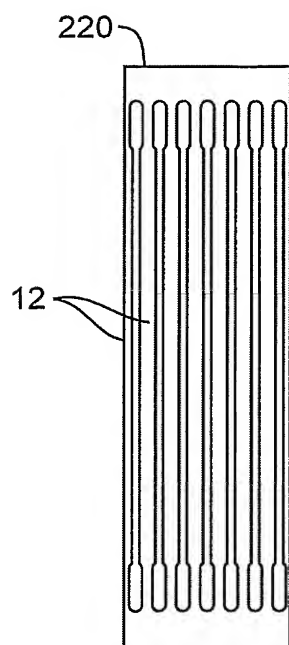


FIG. 15A

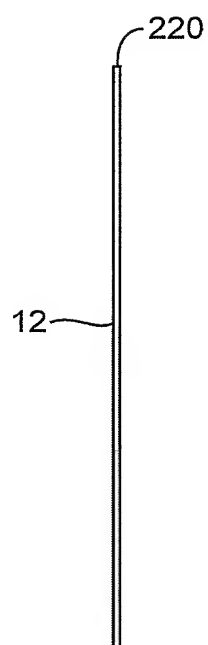


FIG. 15B

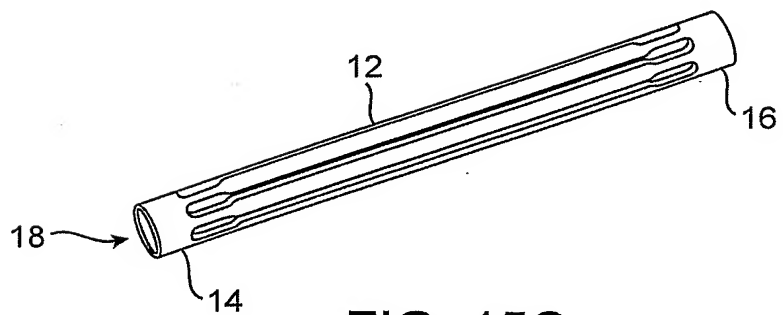


FIG. 15C

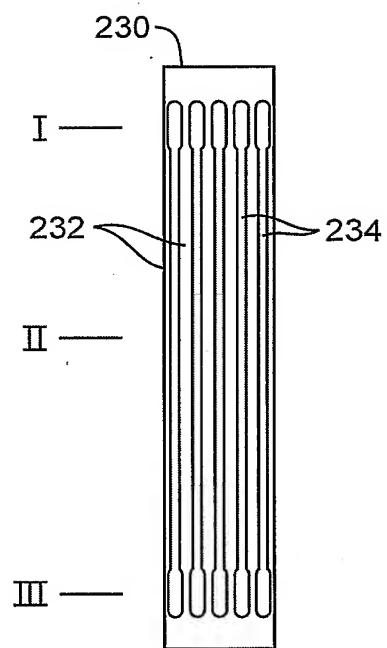


FIG. 16A

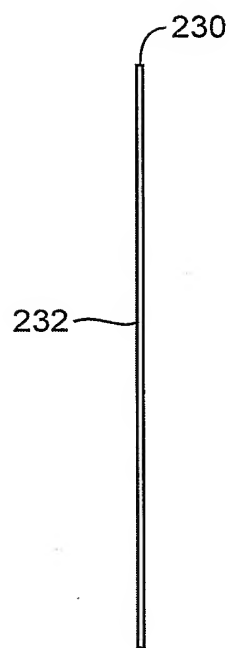


FIG. 16B

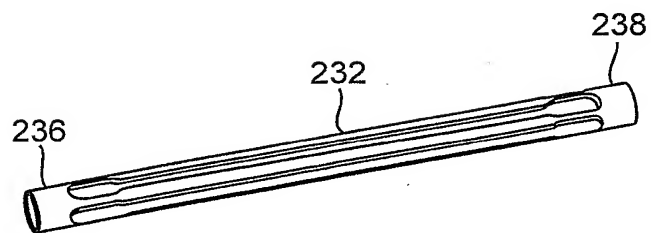


FIG. 16C



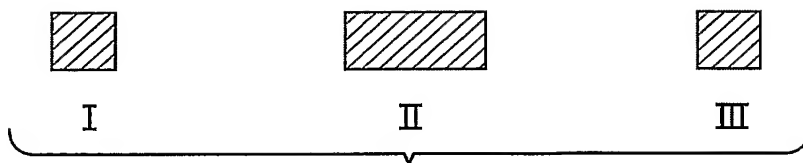


FIG. 17A

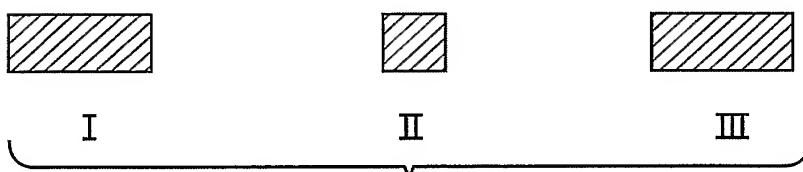


FIG. 17B

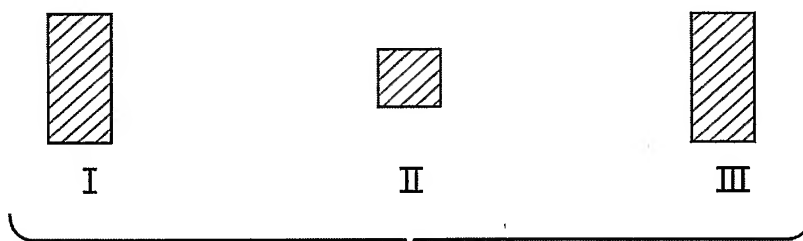


FIG. 17C

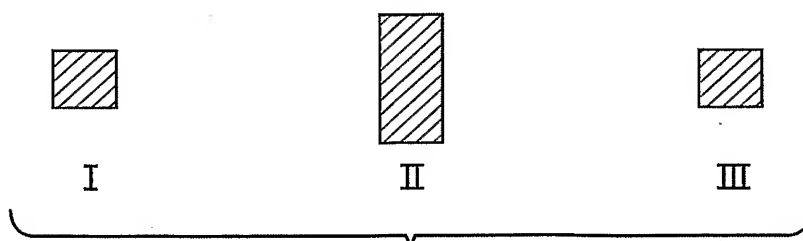


FIG. 17D

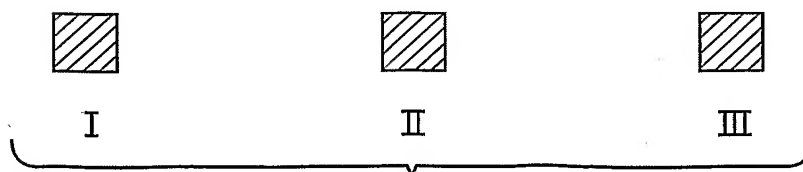


FIG. 17E

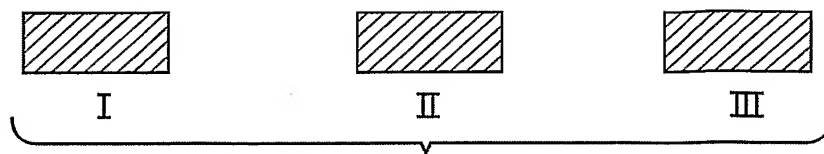


FIG. 17F

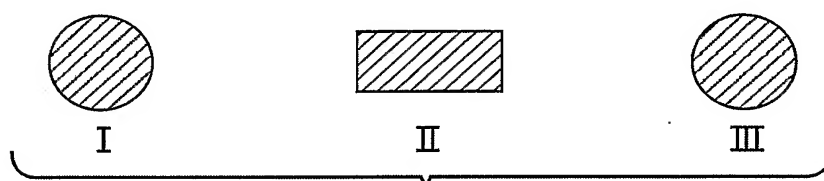


FIG. 17G

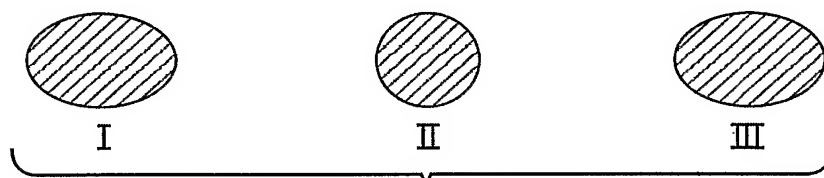


FIG. 17H

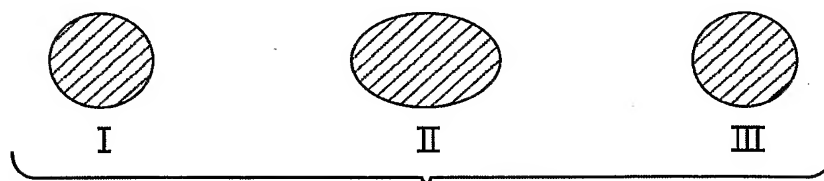


FIG. 17I

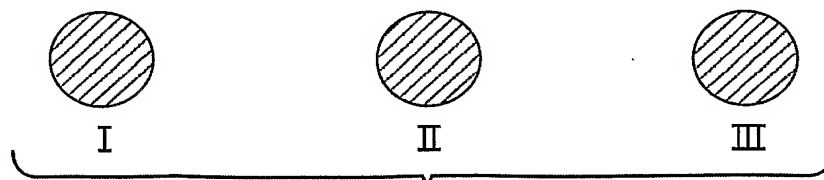


FIG. 17J

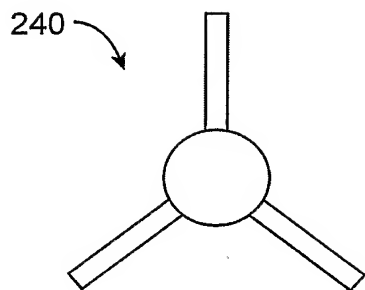


FIG. 18A

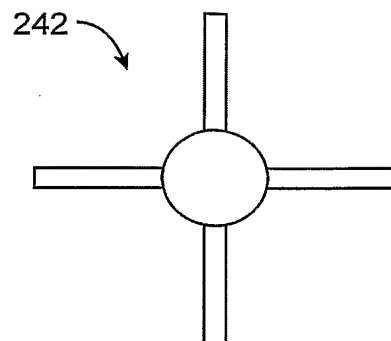


FIG. 18B

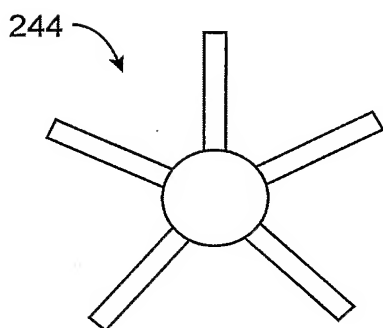


FIG. 18C

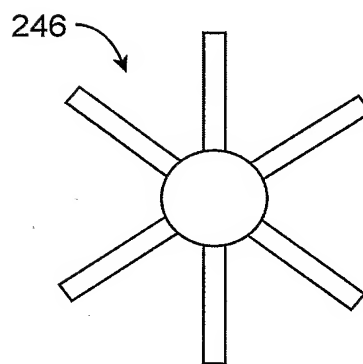


FIG. 18D

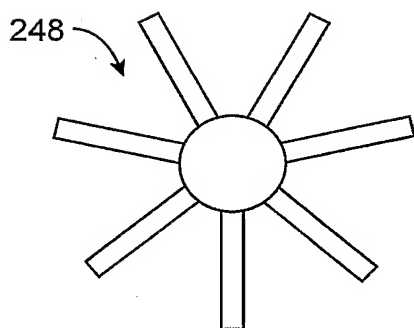


FIG. 18E

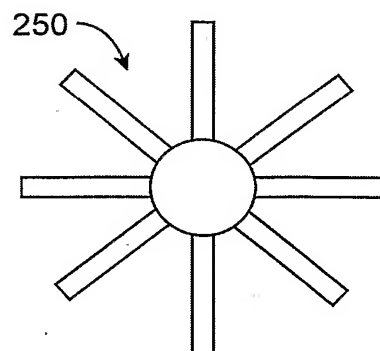


FIG. 18F

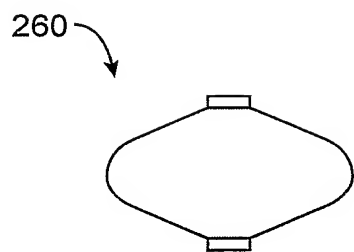


FIG. 19A

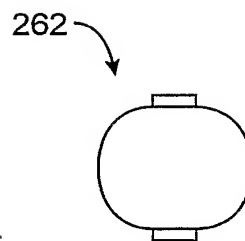


FIG. 19B

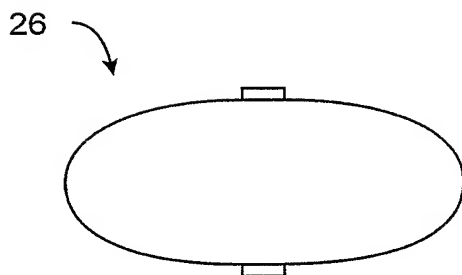


FIG. 19C

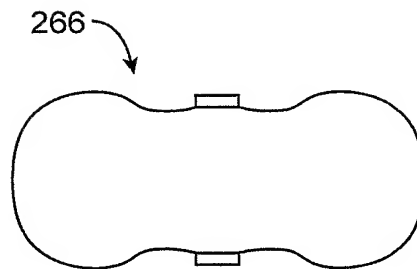


FIG. 19D

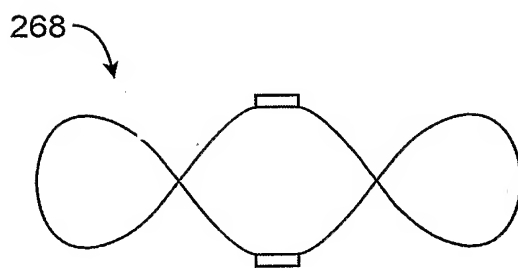


FIG. 19E

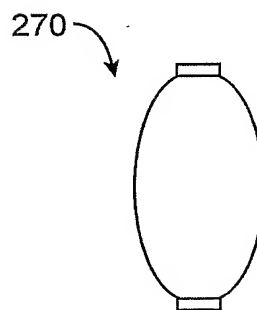


FIG. 19F

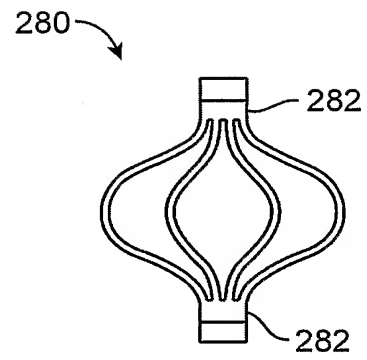


FIG. 20A

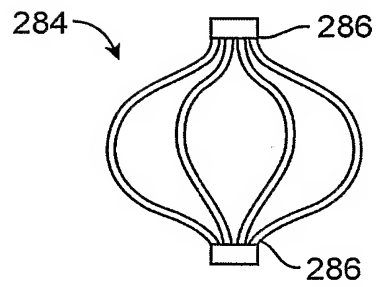


FIG. 20B

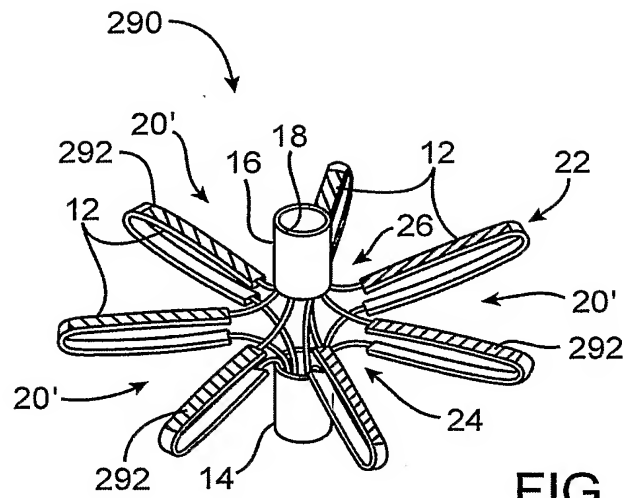


FIG. 21A

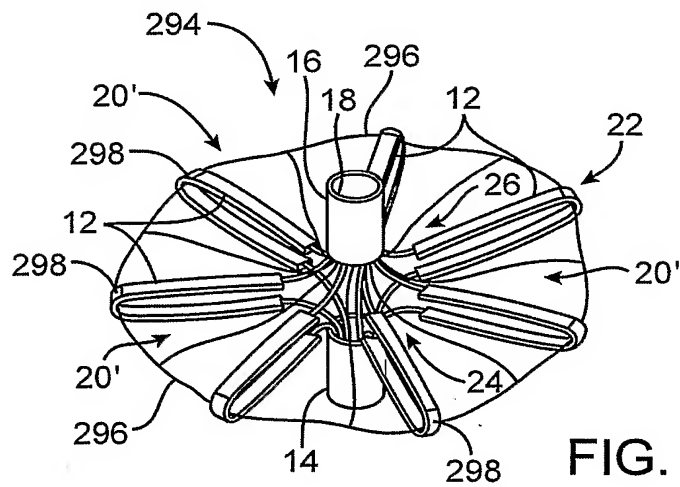


FIG. 21B

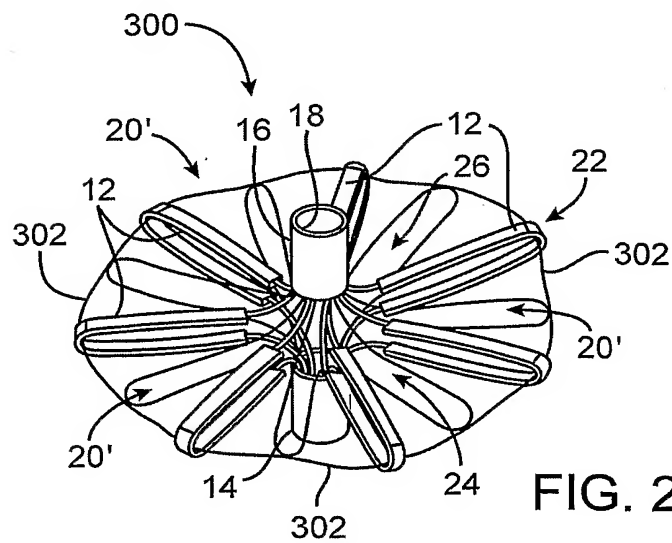


FIG. 21C

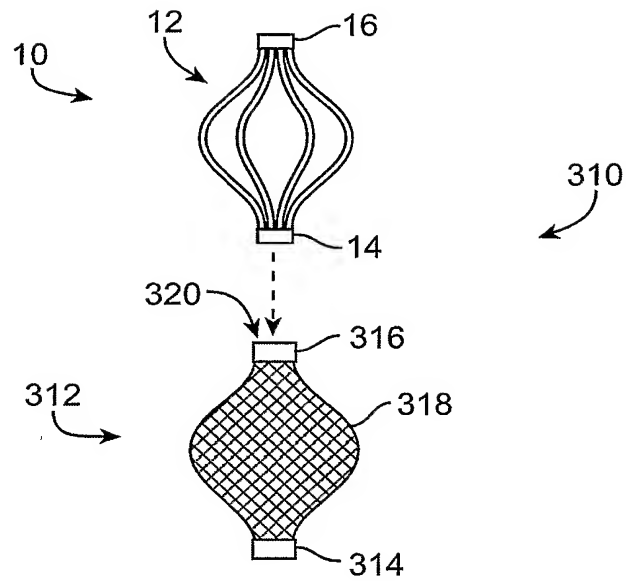


FIG. 22A

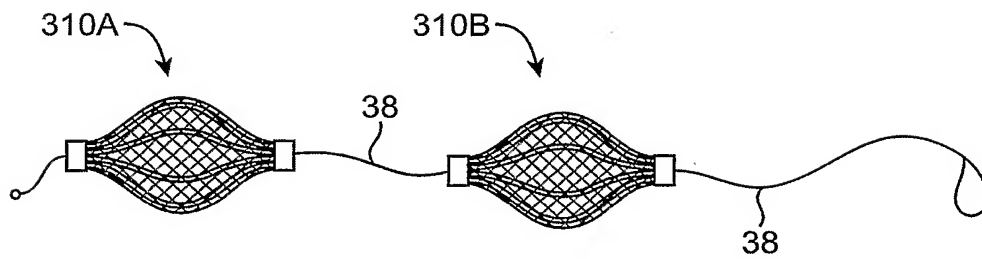


FIG. 22B

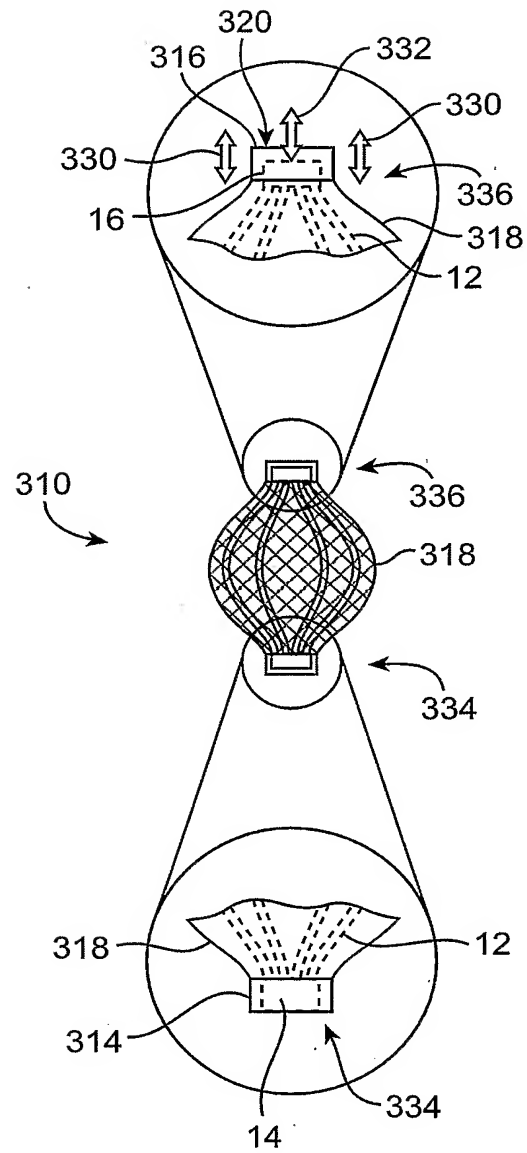


FIG. 23A



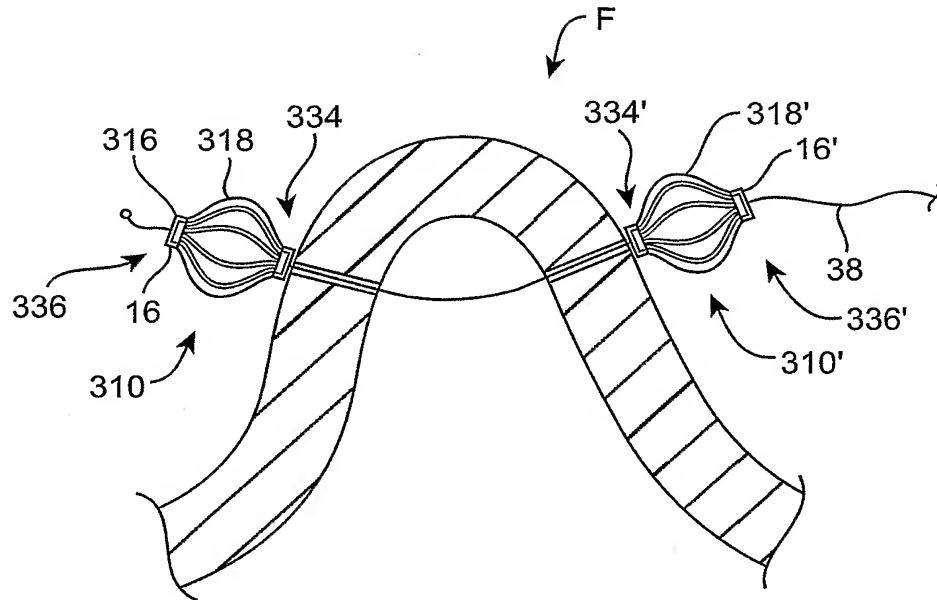


FIG. 23B

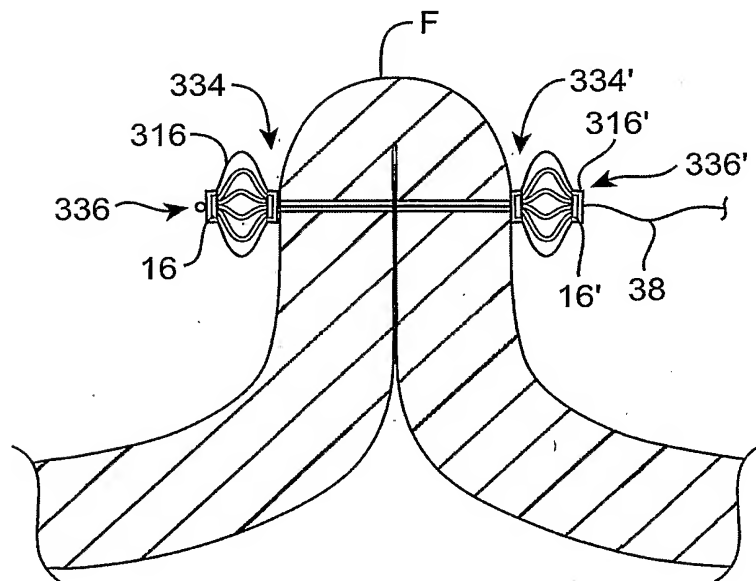


FIG. 23C

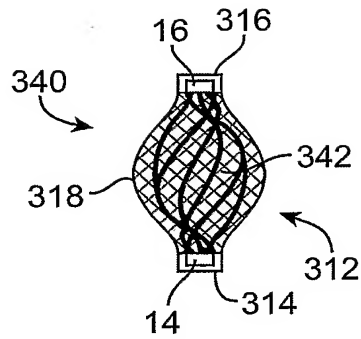


FIG. 24A

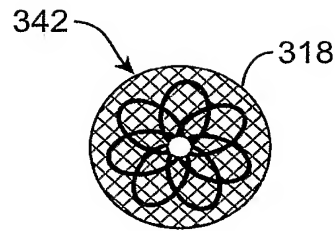


FIG. 24B

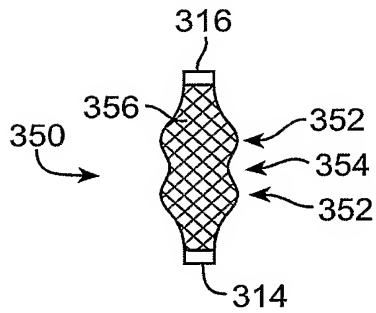


FIG. 25A

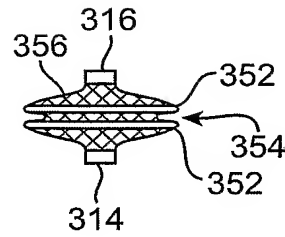


FIG. 25B

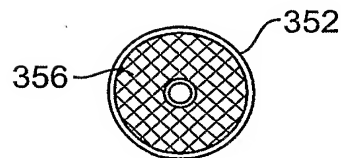


FIG. 25C

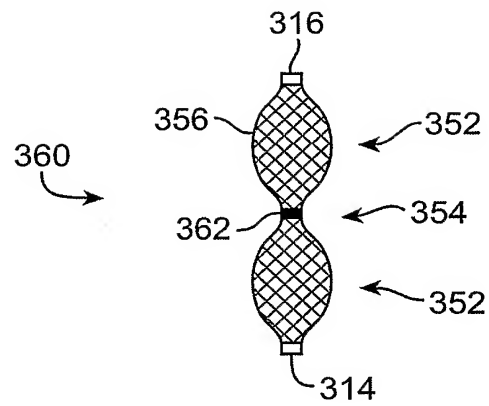


FIG. 26A

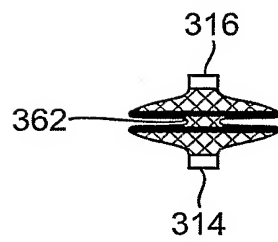


FIG. 26B

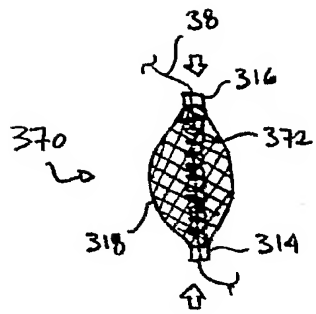


FIG. 27A

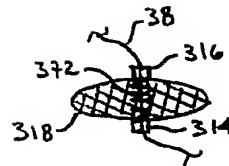


FIG. 27B

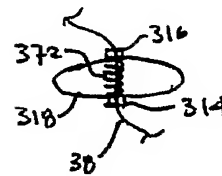


FIG. 27C

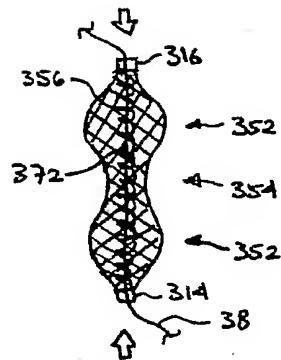


FIG. 28A

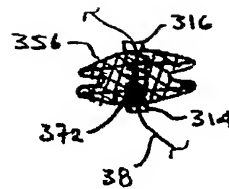


FIG. 28B

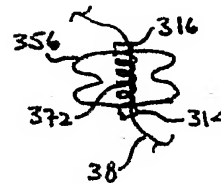


FIG. 28C

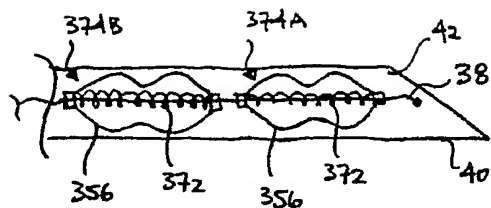


FIG. 29

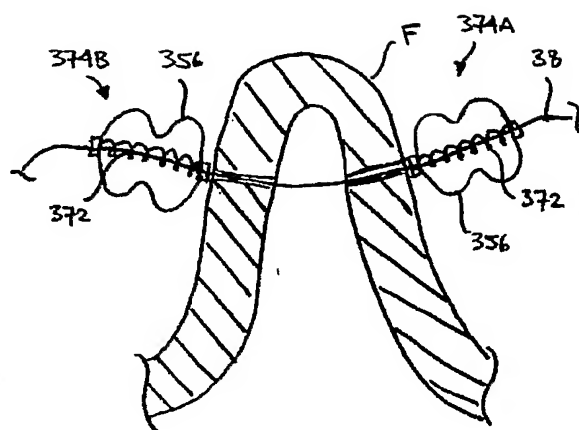


FIG. 30A

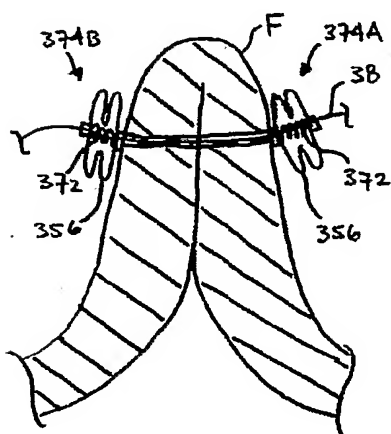


FIG. 30B